

US3332089 (Prod: Foothill Family Clinic)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:21:48

All time stamps listed in this document are displayed in GMT

US3332089

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

[Participant ID](#)

US3332089

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

US3332089

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:36:42

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:36:42

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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 18:36:42

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Condition	BILATERAL KNEE PAIN
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Condition	UMBILICAL HERNIA REPAIR
Start date (dd MMM yyyy)	04 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	04 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Condition	UMBILICAL HERNIA
Start date (dd MMM yyyy)	UN MAY 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)	04 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:52 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:52
Height (<i>xxx.x</i>)	66.3 in
Weight (<i>xxx.x</i>)	201 lb
BMI (<i>xxx.x</i>)	32.21654 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 18:36:42

Generated On: 11 Aug 2021 22:21:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 18:36:42

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Date of assessment (dd MMM yyyy) 17 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 18:36:42

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	17 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)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:36:42

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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 18:36:42

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 114563

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) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

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)	17 SEP 2020
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:52
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

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)	17 SEP 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:20
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

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) 19 Feb 2021 18:36:43

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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) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 10:48 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 10:48

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) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	17 SEP 2020 10:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:12	17 SEP 2020 10:12
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

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 22:21:48

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 11:20

PC Open Date & Time

17 SEP 2020 11:08

PC Close Date & Time

17 SEP 2020 13:38

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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

97.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	17 SEP 2020 19:17
PC Open Date & Time	17 SEP 2020 14:33
PC Close Date & Time	18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	18 SEP 2020 17:20
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

19 SEP 2020 14:59

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 16:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 20:07

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 13:09

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	24 SEP 2020 05:00
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	24 SEP 2020 23:46
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

25 SEP 2020 12:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 SEP 2020 02:35
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 11

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 10:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

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

17 SEP 2020 11:21

PC Open Date & Time

17 SEP 2020 11:08

PC Close Date & Time

17 SEP 2020 13:38

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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

17 SEP 2020 19:17

PC Open Date & Time

17 SEP 2020 14:33

PC Close Date & Time

18 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

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

18 SEP 2020 17:20

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

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

19 SEP 2020 15:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

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

20 SEP 2020 16:56

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

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

21 SEP 2020 20:07

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

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

22 SEP 2020 13:10

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

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

24 SEP 2020 05:01

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 11:23
PC Open Date & Time	17 SEP 2020 11:08
PC Close Date & Time	17 SEP 2020 13:38

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 19:17
PC Open Date & Time	17 SEP 2020 14:33
PC Close Date & Time	18 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

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 ☒

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 17:21
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 15:00
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

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 ☒

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 16:58
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:08
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

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 ☒

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 13:10
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

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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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 05:01
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

24 SEP 2020 23:45

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

25 SEP 2020 12:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

27 SEP 2020 02:35

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

28 SEP 2020 10:09

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

29 SEP 2020 08:50

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

29 SEP 2020 16:24

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

30 SEP 2020 13:21

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 01 OCT 2020 12:59

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

02 OCT 2020 17:16

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

03 OCT 2020 12:25

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 04 OCT 2020 23:59

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 05 OCT 2020 13:35

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

06 OCT 2020 15:42

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 07 OCT 2020 16:30

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

09 OCT 2020 17:22

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time stamp 24 SEP 2020 23:46

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 25 SEP 2020 12:01

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 27 SEP 2020 02:35

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 28 SEP 2020 10:09

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

24 SEP 2020 23:47

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp 25 SEP 2020 12:01

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 23:47
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 SEP 2020 02:35
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 10:09
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

29 SEP 2020 16:24

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 13:21
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 12:59
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 17:16
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 OCT 2020 12:26
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 OCT 2020 23:59
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 13:35
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 15:42
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 16:30
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 22

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 17:23
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 25

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3332089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3332089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

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.

US3332089

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

Was study treatment given? Yes ☐
No ☐

If No, reason not given

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

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

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3332089

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

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

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

US3332089

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

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

NOT DONE. VISIT TWO NOT
COMPLETED PER SPONSOR.

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

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

NOT DONE. VISIT TWO NOT
COMPLETED PER SPONSOR.

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

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

NOT DONE. VISIT TWO NOT
COMPLETED PER SPONSOR.

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:42

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:37:59

Generated On: 11 Aug 2021 22:21:48

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:37:59

Generated On: 11 Aug 2021 22:21:48

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3332089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:37:59

Generated On: 11 Aug 2021 22:21:48

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.

US3332089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:37:59

Generated On: 11 Aug 2021 22:21:48

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3332089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:36:43

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 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"/>

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 68
Have 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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 75
Have 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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 82

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

No ☒

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 06:26:09

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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="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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 10:14:22
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	19 JAN 2021 06:21:06
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 20:51:32

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	30 JAN 2021 06:55:13
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 16:34:10
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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	15 FEB 2021 17:02:35
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 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	22 FEB 2021 07:34:11
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 09:44:59
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 06:37:10

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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	13 MAR 2021 06:56:56
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 06:24:44

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 09:32:18

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 14:55:05

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 11:37:25

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
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"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message 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	17 APR 2021 05:41:07
Patient Cloud Open Date & Time	17 APR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
161 of 3208	

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

26 APR 2021 07:07:42

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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	03 MAY 2021 22:52:57
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 <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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 257

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

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

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

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

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

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

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 ☐

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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="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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 <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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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°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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 <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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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°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 ☐

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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="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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

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16 FEB 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 <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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 FEB 2022 00:01

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23 FEB 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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09 MAR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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30 MAR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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20 APR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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="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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

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17 AUG 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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07 SEP 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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°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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3332089

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:21:48

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 09:45:09

US3332089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3332089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 MAR 2021

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

US3332089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

09:58 (24 HR)

Collection date and time (derived)

2 MAR 2021 09:58

US3332089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

Date of Contact	15 APR 2021
Time of Contact	10:40
Date and Time of Contact (derived)	15 APR 2021 10:40
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>

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

	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 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

347 of 3208

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 15 Apr 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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 15 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Apr 2021 19:41:41

Generated On: 11 Aug 2021 22:21:48

Date of Visit	15 APR 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	15 APR 2021
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 checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	LAB CORPS
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Data signed: (b) (4) 19 Apr 2021 19:41:41

Generated On: 11 Aug 2021 22:21:48

Date of Contact	15 APR 2021
Time of Contact	10:40
Date and Time of Contact (derived)	15 APR 2021 10:40
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>

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Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Apr 2021 19:41:41

Generated On: 11 Aug 2021 22:21:48

Date of Visit	15 APR 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	15 APR 2021
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 checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	LABCORPS
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

Date of Contact	25 SEP 2020
Time of Contact	08:00
Date and Time of Contact (derived)	25 SEP 2020 08:00
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 SEP 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 25 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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"/>

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 25 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 25 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 (4)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 SEP 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	97.0 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

Date	30 SEP 2020
------	-------------

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

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

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

Temperature	97.4 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 (7)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 25 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" 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 Feb 2021 13:36:28

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 13:36:28

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input 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 (8)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:36:28

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input 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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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:36:28

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:36:28

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Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:36:28

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 (11)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 type="radio"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 25 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		407 of 3208
EAB) (1725)		

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 (16)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Form: Symptom Log (17)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (17)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 25 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Form: Symptom Log (19)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		431 of 3208
EAB) (1725)		

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 25 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 (20)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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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Form: Symptom Log (20)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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		435 of 3208
EAB) (1725)		

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 25 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 (21)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Form: Symptom Log (21)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Form: Symptom Log (21)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 25 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

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Form: Symptom Log (22)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 25 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 25 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 25 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 25 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 25 Sep 2020

Form: Symptom Log (23)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

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 25 Sep 2020

Form: Symptom Log (24)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 25 Sep 2020

Form: Symptom Log (24)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 25 Sep 2020

Form: Symptom Log (24)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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 25 Sep 2020

Form: Symptom Log (25)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Symptom Day

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

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 25 Sep 2020

Form: Symptom Log (25)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" 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 25 Sep 2020

Form: Symptom Log (25)

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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 25 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

Date of Visit	25 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	25 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

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Data signed: (b) (4) 23 Feb 2021 13:36:27

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Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 13:36:28

Generated On: 11 Aug 2021 22:21:48

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 SEP 2020
Day 5	Yes	29 SEP 2020
Day 7	Yes	01 OCT 2020
Day 9	Yes	02 OCT 2020
Day 14	Yes	07 OCT 2020
Day 21	Yes	15 OCT 2020
Day 28	Yes	26 OCT 2020

US3332089

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 11 Aug 2021 22:21:48

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3332089

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	19:23 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 19:23
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3332089

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 SEP 2020

US3332089

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 APR 2021
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	15 APR 2021 14:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 APR 2021

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

US3332089

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 15:50:34

Generated On: 11 Aug 2021 22:21:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 APR 2021

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 09:55
Height (xxx.x)	66.3 in
Weight (xxx.x)	205.0 lb
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3332089

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

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.

US3332089

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:21:48

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3332089

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

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

Visit date (dd MMM yyyy)	11 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3332089

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 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>)	11 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3332089

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3332089

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

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)	11 JAN 2021
Time of assessment (00:00-23:59)	10:03 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:03
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3332089

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

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)	11 JAN 2021
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:58
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3332089

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3332089

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

Form: Pregnancy Test

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	11 JAN 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)	

US3332089

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

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) 11 JAN 2021

What was the treatment time? (00:00-23:59) 10:28 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 10:28

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

What was the frequency of the study treatment dosing? ONCE

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

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	09:38 (24 HR)
Collection date and time (derived)	11 JAN 2021 09:38

US3332089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	09:35
Collection Date and Time (derived)	11 JAN 2021 09:35

US3332089

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:36:45

Generated On: 11 Aug 2021 22:21:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:36:45

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 11:05
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332089

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3332089

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00-23:59)	11:08 (24 HR)
Collection date and time (derived)	9 FEB 2021 11:08

US3332089

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3332089

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 22:30:08

Generated On: 11 Aug 2021 22:21:48

AEID	USA-US202-2020-MRNA-1273-P30 1000001
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	18 SEP 2020
Start time (00:00-23:59)	21:46 (24 HR)
AE start date and time (derived)	18 SEP 2020 21:46
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 OCT 2020
End time (00:00-23:59)	08:00 (24 HR)
AE End Date and Time (derived)	09 OCT 2020 08:00
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3332089

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 22:30:08

Generated On: 11 Aug 2021 22:21:48

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 22:30:08

Generated On: 11 Aug 2021 22:21:48

AEID

Adverse event

STOMACH PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

30 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

2 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 22:30:08

Generated On: 11 Aug 2021 22:21:48

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

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 22:30:08

Generated On: 11 Aug 2021 22:21:48

AEID	
Adverse event	WORSENING OF INSOMNIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 22:30:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 22:30:08

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AEID	
Adverse event	WORSENING OF DEPRESSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 22:30:08

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 22:30:08

Generated On: 11 Aug 2021 22:21:48

AEID	
Adverse event	COVID-LIKE ILLNESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 22:30:08

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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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 13:36:27

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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Name of Medication BUPROPION

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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Name of Medication GLUCOSAMINE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE PAIN

Dose per administration 1500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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Name of Medication	TYLENOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	INJECTION SITE PAIN, MUSCLE ACHES
Dose per administration	100
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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Name of Medication THERAFLU (ACETAMINOPHEN,
DIPHENHYDRAMINE,
PHENYLEPHRINE)

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 1

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

If dose unit is Other, specify PACKET

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	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)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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Name of Medication MIDOL (ACETAMINOPHEN,
CAFFEINE, PYRILAMINE)

Prophylaxis Yes ☐
No ☒

Indication STOMACH PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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Name of Medication MIRENA

Prophylaxis Yes ☒
No ☐

Indication PREGNANCY PROPHYLAXIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	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)	UN JUL 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 00:15:00

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Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	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)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	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)		24 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 5 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

Name of Medication LEXAPRO

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 Apr 2021 00:15:00

Generated On: 11 Aug 2021 22:21:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 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"/>

US3332089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 13:36:27

Generated On: 11 Aug 2021 22:21:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3332089

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

Date of dosing discontinuation (dd MMM yyyy) 18 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3332089

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:21:48

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 ☐

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

SAEID	USA-US202-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

SAEID	USA-US202-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/SEP/2020 12:20
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

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

SAEID	USA-US202-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/OCT/2020 15:53
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

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

SAEID	USA-US202-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/OCT/2020 13:25
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

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

SAEID	USA-US202-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/OCT/2020 14:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 13:36:29

Generated On: 11 Aug 2021 22:21:48

SAEID	USA-US202-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMES
Investigator's Last Name	PETERSON
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	27/OCT/2020 16:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3332089 (Prod: Foothill Family Clinic)

US3332089

Form: Participant Creation

Generated On: 11 Aug 2021 22:21:48

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:49
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'US3332089'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:19:31

US3332089

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:07:59
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:40:22
	(b) (4)	

US3332089

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:08:00
User entered '17 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:19:32

US3332089

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[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 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:08:02
User entered 'Clinic (Clinic)'	Ty Henry (b) (4)	17 Sep 2020 17:40:22
	(b) (4)	

US3332089

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'SCRN'	System	17 Sep 2020 17:40:22

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:11:10
User entered (b) (6) 1978'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:19:33

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:11:36
User entered '42'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'YEARS'	System	17 Sep 2020 17:40:48

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '42'	System	17 Sep 2020 17:13:34

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:11:40
User entered 'Female (F)'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:11:34
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:11:33
User entered 'l'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:32
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:32
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:32
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:32
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:32
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:32
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:32
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:21:48

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:32
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:40:48
	(b) (4)	

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:09:55
User entered '17 Sep 2020'	Megan Grimmatt (b) (4)	17 Sep 2020 17:13:34
	(b) (4)	

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'Sep 2020'	System	17 Sep 2020 17:13:34

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '2020'	System	17 Sep 2020 17:13:34

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:09:58
User entered 'Amendment 3 (3)'	Megan Grimmatt (b) (4)	17 Sep 2020 17:13:34
	(b) (4)	

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:10:00
User entered 'Yes (Y)'	Megan Grimmett (b) (4)	17 Sep 2020 17:13:34
	(b) (4)	

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:41
User entered empty.	Megan Grimmett (b) (4)	17 Sep 2020 17:13:34
	(b) (4)	

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:41
User entered empty.	Megan Grimmatt (b) (4)	17 Sep 2020 17:13:34
	(b) (4)	

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:10:03
User entered 'No (N)'	Megan Grimmatt (b) (4)	17 Sep 2020 17:13:34
	(b) (4)	

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:57:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:19:32

US3332089

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:21:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '1'	System	17 Sep 2020 17:13:40

US3332089

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:21:48

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:10:11
User entered 'Yes (Y)'	Megan Grimmett (b) (4)	17 Sep 2020 17:13:40
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:21:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:10:40
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:41:13
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:13:19
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:42:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:42:48
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 17:42:02
User entered 'Depression'	Ty Henry (b) (4)	17 Sep 2020 17:41:32
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:13:26
User entered 'un UNK 2002'	Ty Henry (b) (4)	17 Sep 2020 17:41:32
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:41:32
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:13:31
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:41:32
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:41:32
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:41:32
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'Jan 2002'	System	17 Sep 2020 17:41:32

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '2002'	System	17 Sep 2020 17:41:32

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered empty.	System	17 Sep 2020 17:41:32

US3332089

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:21:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered empty.	System	17 Sep 2020 17:41:32

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:13:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:42:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:42:47
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 17:42:02
User entered 'Bilateral Knee Pain'	Ty Henry (b) (4)	17 Sep 2020 17:41:50
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:13:39
User entered 'un UNK 2012'	Ty Henry (b) (4)	17 Sep 2020 17:41:50
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
DataPoint Un-verified.		30 Oct 2020 20:13:45
DataPoint Verified.		30 Oct 2020 20:13:42
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:41:50
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:13:48
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:41:50
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:41:50
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:41:50
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'Jan 2012'	System	17 Sep 2020 17:41:50

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '2012'	System	17 Sep 2020 17:41:50

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered empty.	System	17 Sep 2020 17:41:50

US3332089

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:21:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered empty.	System	17 Sep 2020 17:41:50

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:14:03
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Umbilical hernia repair, LLT: Umbilical hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 04:58:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 04:58:46
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 17:43:02
User entered 'Umbilical Hernia Repair'	Ty Henry (b) (4)	17 Sep 2020 17:42:23
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:14:16
User entered '04 Aug 2020'	Ty Henry (b) (4)	17 Sep 2020 17:42:23
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:42:23
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:14:18
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:42:23
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:14:20
User entered '04 Aug 2020'	Ty Henry (b) (4)	17 Sep 2020 17:42:23
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:42:23
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'Aug 2020'	System	17 Sep 2020 17:42:23

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '2020'	System	17 Sep 2020 17:42:23

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'Aug 2020'	System	17 Sep 2020 17:42:23

US3332089

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:21:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '2020'	System	17 Sep 2020 17:42:23

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:14:34
User coded data point as SOC: Gastrointestinal disorders, HLG: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 04:59:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 04:59:47
	(b) (4)	
Data point term sent to Coder	System	17 Sep 2020 17:44:05
User entered 'Umbilical Hernia'	Ty Henry (b) (4)	17 Sep 2020 17:43:10
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:14:41
User entered 'un May 2020'	Ty Henry (b) (4)	17 Sep 2020 17:43:10
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:43:10
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:14:46
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:43:10
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:14:48
User entered '04 Aug 2020'	Ty Henry (b) (4)	17 Sep 2020 17:43:10
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:07
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:43:10
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'May 2020'	System	17 Sep 2020 17:43:10

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '2020'	System	17 Sep 2020 17:43:10

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'Aug 2020'	System	17 Sep 2020 17:43:10

US3332089

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:21:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '2020'	System	17 Sep 2020 17:43:10

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 15:11:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 15:11:34
Data point term sent to Coder	System	25 Mar 2021 15:10:24
User entered 'Insomnia'	Kenadie Hamblin (b) (4)	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'un UNK 2018'	Kenadie Hamblin (b) (4)	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered '0'	Kenadie Hamblin (b) (4)	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
	(b) (4)	
User entered empty.	Kenadie Hamblin (b) (4)	25 Mar 2021 15:09:30
	(b) (4)	

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:36:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered '0'	Kenadie Hamblin (b) (4)	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'Jan 2018'	System	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '2018'	System	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered empty.	System	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:21:48

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered empty.	System	25 Mar 2021 15:09:30

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:12:16
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:12:20
User entered '17 Sep 2020'	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:12:30
User closed query 'Per CDM: Please confirm if time 09:52 is AM or PM. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:25:51
Query 'Per CDM: Please confirm if time 09:52 is AM or PM. Thank you.' answered with '09:52 AM' (Site from DM).	Ty Henry (b) (4)	25 Sep 2020 21:32:34
	(b) (4)	
User opened query 'Per CDM: Please confirm if time 09:52 is AM or PM. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:43:48
User entered '09:52'	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '17 Sep 2020 09:52'	System	17 Sep 2020 17:44:09

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:12:33
User entered '66.3' in	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	
DataPoint set to visible.	System	17 Sep 2020 17:13:40

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:12:35
User entered '201' lb	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	
DataPoint set to visible.	System	17 Sep 2020 17:13:40

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered '32.21654'	System	17 Sep 2020 17:44:09
DataPoint set to visible.	System	17 Sep 2020 17:13:40

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'kg/m2'	System	17 Sep 2020 17:44:09
DataPoint set to visible.	System	17 Sep 2020 17:13:40

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:18
User entered missing code ND - Not Done.	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:18
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:18
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:18
User entered missing code ND - Not Done.	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'bpm'	System	17 Sep 2020 17:44:09

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:18
User entered missing code ND - Not Done.	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'breaths/min'	System	17 Sep 2020 17:44:09

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:18
User entered missing code ND - Not Done.	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'mmHg'	System	17 Sep 2020 17:44:09

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:18
User entered missing code ND - Not Done.	Ty Henry (b) (4)	17 Sep 2020 17:44:09
	(b) (4)	

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered 'mmHg'	System	17 Sep 2020 17:44:09

US3332089

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34

US3332089

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:05
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:45:08
	(b) (4)	

US3332089

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:07
User entered '17 Sep 2020'	Ty Henry (b) (4)	17 Sep 2020 17:45:08
	(b) (4)	

US3332089

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:15
User entered '17 Sep 2020'	Ty Henry (b) (4)	17 Sep 2020 17:45:36
	(b) (4)	

US3332089

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:21:48

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:17
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:45:36
	(b) (4)	

US3332089

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:21:48

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:29
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:45:36
	(b) (4)	

US3332089

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:21:48

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:29
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:45:36
	(b) (4)	

US3332089

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:29
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:45:36
	(b) (4)	

US3332089

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:21:48

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:29
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:45:36
	(b) (4)	

US3332089

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:29
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:45:36
	(b) (4)	

US3332089

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:21:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:29
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:45:36
	(b) (4)	

US3332089

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:29
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:46:22
	(b) (4)	

US3332089

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:31
User entered '17 Sep 2020'	Ty Henry (b) (4)	17 Sep 2020 17:46:22
	(b) (4)	

US3332089

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:32
User entered 'Urine (URINE)'	Ty Henry (b) (4)	17 Sep 2020 17:46:22
	(b) (4)	

US3332089

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:34
User entered 'Negative (NEGATIVE)'	Ty Henry (b) (4)	17 Sep 2020 17:46:22
	(b) (4)	

US3332089

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:15:36
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:22
	(b) (4)	

US3332089

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:36
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:46:22
	(b) (4)	

US3332089

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:36
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:46:22
	(b) (4)	

US3332089

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User entered empty.	System	17 Sep 2020 17:46:22

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:43
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:45
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:46
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:47
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:50
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:51
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:53
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:54
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:57
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:16:59
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:17:01
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:17:03
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:42
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:42
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:42
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:42
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:42
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:17:05
User entered 'I'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:21:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:24:34
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:58:42
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:46:57
	(b) (4)	

US3332089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:17:17
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:47:11

US3332089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:17:18
User entered '17 Sep 2020'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:47:11

US3332089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[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 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:17:20
User entered 'Clinic (Clinic)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:47:11

US3332089

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'VISIT1'	System	17 Sep 2020 17:47:11

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4)	10 Nov 2020 06:58:58
User entered '17 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:24:12

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4)	10 Nov 2020 06:58:58
User entered '114563'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:24:12

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:18:35
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 16:24:12

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

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 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:45:25
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:47:27

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

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 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:45:26
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:47:27

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:45:28
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:47:27

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:45:29
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:47:27

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:45:40
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:47:27

US3332089

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:21:48

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 07:09:14
DataPoint Verified.		23 Nov 2020 20:33:19
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with '.' (Site from DM).		23 Nov 2020 20:19:05
User entered 'No (N)'		23 Nov 2020 20:19:01
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).		20 Nov 2020 20:24:01
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:25:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:25:37

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:04
User entered missing code ND - Not Done.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:04
User entered missing code ND - Not Done.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:04
User entered missing code ND - Not Done.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:04
User entered missing code ND - Not Done.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User accepted default value 'Pre-Dose (PREDOSE)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:18
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:16
User entered '17 Sep 2020'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:14
User entered '09:52'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered '17 Sep 2020 09:52'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:24
User entered '98.2' F	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:26
User entered 'Oral (Oral)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:04
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:29
User entered '70'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'bpm'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:31
User entered '16'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'breaths/min'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:35
User entered '106'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'mmHg'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:41:36
User entered '67'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'mmHg'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:04
User entered missing code ND - Not Done.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:04
User entered missing code ND - Not Done.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User accepted default value 'Post-Dose (POSTDOSE)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:20:47
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:20:49
User entered '17 Sep 2020'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:20:51
User entered '11:20'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered '17 Sep 2020 11:20'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:20:55
User entered '98.1' F	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:20:57
User entered 'Oral (Oral)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:04
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:21:05
User entered '67'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'bpm'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:21:07
User entered '16'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'breaths/min'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:21:25
User entered '118'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'mmHg'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:21:23
User entered '72'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'mmHg'	System	17 Sep 2020 17:49:42

US3332089

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:39:03
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:30

US3332089

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:59:11
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:50:30

US3332089

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:28
User closed query ' Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:06:00
Query ' Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.Thank you. ' answered with 'u' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:25:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 21:25:34
User opened query ' Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:50:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:27:34
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:36

US3332089

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:28
User entered empty; reason for change Data Entry Error		06 Nov 2020 21:25:34
User entered '17 Sep 2020' reason for change: Data Entry Error		30 Oct 2020 16:27:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:36

US3332089

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:28
User entered empty; reason for change Data Entry Error		06 Nov 2020 21:25:34
User entered 'Urine (URINE)' reason for change: Data Entry Error		30 Oct 2020 16:27:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:36

US3332089

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:28
User entered empty; reason for change Data Entry Error		06 Nov 2020 21:25:34
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error		30 Oct 2020 16:27:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:36

US3332089

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4)	10 Nov 2020 06:59:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 21:25:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:27:34
User entered empty.	Ty Henry (b) (4)	17 Sep 2020 17:50:36

US3332089

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:28
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:36

US3332089

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:28
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:36

US3332089

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered empty.	System	17 Sep 2020 17:50:36

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:42:42
User entered 'Yes (Y)'	Megan Grimmatt (b) (4)	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:59:34
User entered empty.	Megan Grimmatt (b) (4)	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

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 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 06:59:34
User entered empty.	Megan Grimmett (b) (4)	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:42:48
User entered '17 Sep 2020'	Megan Grimmatt (b) (4)	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:42:49
User entered '10:48'	Megan Grimmatt (b) (4)	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered '17 Sep 2020 10:48'	System	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:42:51
User entered 'Left Arm (LEFT ARM)'	Megan Grimmatt (b) (4)	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:42:53
User entered 'ONCE'	System	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 17:14:06

US3332089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:46:26
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:55

US3332089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 17-SEP-2020. However, test result date is missing in GCL. Please confirm if 17-SEP-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:39:59
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 17-SEP-2020. However, test result date is missing in GCL. Please confirm if 17-SEP-2020 is correct date to update in GCL records.' answered with 'i confirm date of collection was 9.17.2020' (Site from DM).	Colby Bostock (b) (4) (b) (4)	12 Nov 2020 16:40:26
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 17-SEP-2020. However, test result date is missing in GCL. Please confirm if 17-SEP-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:53:20
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:46:28
User entered '17 Sep 2020'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:55

US3332089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:46:29
User entered '10:15'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:50:55

US3332089

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered '17 Sep 2020 10:15'	System	17 Sep 2020 17:50:55

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:21:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:46:50
User entered '17 Sep 2020'	Ty Henry (b) (4)	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:21:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:21:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:46:47
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:21:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:46:49
User entered '10:12'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered '17 Sep 2020 10:12'	System	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:21:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:21:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:47
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:21:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 06:59:47
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered empty.	System	17 Sep 2020 17:51:20

US3332089

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:47:01
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:51:26

US3332089

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered '1'	System	17 Sep 2020 17:51:26

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:19:21', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'bc43ce79-4129-4be7-b460-4387d7ebff0'	System	17 Sep 2020 17:20:22
User entered 'Yes (Y)'	System	17 Sep 2020 17:20:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:19:57', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'bc43ce79-4129-4be7-b460-4387d7ebff0'	System	17 Sep 2020 17:20:22
User entered '98.1'	System	17 Sep 2020 17:20:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:20:13', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'bc43ce79-4129-4be7-b460-4387d7ebff0'	System	17 Sep 2020 17:20:22
User entered 'No (N)'	System	17 Sep 2020 17:20:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:20:20', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'bc43ce79-4129-4be7-b460-4387d7ebff0'	System	17 Sep 2020 17:20:22
User entered '17 Sep 2020 11:20'	System	17 Sep 2020 17:20:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 11:08'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 13:38'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:16:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c4e1711d-195a-45a4-81ba-c01086076c10' User entered 'Yes (Y)'	System	18 Sep 2020 01:17:24
	System	18 Sep 2020 01:17:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:05', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c4e1711d-195a-45a4-81ba-c01086076c10' User entered '97.1'	System	18 Sep 2020 01:17:24
	System	18 Sep 2020 01:17:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:09', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c4e1711d-195a-45a4-81ba-c01086076c10' User entered 'No (N)'	System	18 Sep 2020 01:17:24
	System	18 Sep 2020 01:17:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:12', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c4e1711d-195a-45a4-81ba-c01086076c10' User entered '17 Sep 2020 19:17'	System	18 Sep 2020 01:17:24
	System	18 Sep 2020 01:17:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 14:33'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 2'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:02', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2075f80f-a863-4290-a3ce-393e9713b920'	System	18 Sep 2020 23:20:24
User entered 'Yes (Y)'	System	18 Sep 2020 23:20:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:07', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2075f80f-a863-4290-a3ce-393e9713b920' User entered '98.0'	System	18 Sep 2020 23:20:24
	System	18 Sep 2020 23:20:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:10', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2075f80f-a863-4290-a3ce-393e9713b920'	System	18 Sep 2020 23:20:24
User entered 'Yes (Y)'	System	18 Sep 2020 23:20:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will confirm with subject during followup tc' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:32:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Colby Bostock (b) (4)	18 Sep 2020 23:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:15', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2075f80f-a863-4290-a3ce-393e9713b920'	(b) (4)	
User entered '1'	System	18 Sep 2020 23:20:24
	System	18 Sep 2020 23:20:24
	System	18 Sep 2020 23:20:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:15', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2075f80f-a863-4290-a3ce-393e9713b920' User entered '0'	System	18 Sep 2020 23:20:24
	System	18 Sep 2020 23:20:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:19', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2075f80f-a863-4290-a3ce-393e9713b920'	System	18 Sep 2020 23:20:24
User entered '18 Sep 2020 17:20'	System	18 Sep 2020 23:20:24

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 3'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T14:59:40', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ed7d042f-b1ae-4bce-8f84-0ea4f6d8bfdd' User entered 'Yes (Y)'	System	19 Sep 2020 21:00:04
	System	19 Sep 2020 21:00:04

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T14:59:46', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ed7d042f-b1ae-4bce-8f84-0ea4f6d8bfdd' User entered '97.3'	System	19 Sep 2020 21:00:04
	System	19 Sep 2020 21:00:04

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T14:59:53', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ed7d042f-b1ae-4bce-8f84-0ea4f6d8bfdd'	System	19 Sep 2020 21:00:04
User entered 'No (N)'	System	19 Sep 2020 21:00:04

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T14:59:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ed7d042f-b1ae-4bce-8f84-0ea4f6d8bfdd'	System	19 Sep 2020 21:00:04
User entered '19 Sep 2020 14:59'	System	19 Sep 2020 21:00:04

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 4'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:55:54', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ac7b0c27-0f26-4d97-8a80-0df722099705' User entered 'Yes (Y)'	System	20 Sep 2020 22:56:10
	System	20 Sep 2020 22:56:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:55:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ac7b0c27-0f26-4d97-8a80-0df722099705' User entered '97.1'	System	20 Sep 2020 22:56:10
	System	20 Sep 2020 22:56:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:56:02', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ac7b0c27-0f26-4d97-8a80-0df722099705'	System	20 Sep 2020 22:56:10
User entered 'No (N)'	System	20 Sep 2020 22:56:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:56:05', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ac7b0c27-0f26-4d97-8a80-0df722099705'	System	20 Sep 2020 22:56:10
User entered '20 Sep 2020 16:56'	System	20 Sep 2020 22:56:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 5'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:02', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8c52e4a2-b1ba-4be6-8c20-ae9a58025229' User entered 'Yes (Y)'	System	22 Sep 2020 02:07:19
	System	22 Sep 2020 02:07:19

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8c52e4a2-b1ba-4be6-8c20-ae9a58025229' User entered '97.3'	System	22 Sep 2020 02:07:19
	System	22 Sep 2020 02:07:19

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:09', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8c52e4a2-b1ba-4be6-8c20-ae9a58025229' User entered 'No (N)'	System	22 Sep 2020 02:07:19
	System	22 Sep 2020 02:07:19

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:15', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8c52e4a2-b1ba-4be6-8c20-ae9a58025229'	System	22 Sep 2020 02:07:19
User entered '21 Sep 2020 20:07'	System	22 Sep 2020 02:07:19

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 6'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:09:43', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '485b7904-98c5-4a07-9b0b-2c3252da88cd' User entered 'Yes (Y)'	System	22 Sep 2020 19:10:00
	System	22 Sep 2020 19:10:00

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:09:49', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '485b7904-98c5-4a07-9b0b-2c3252da88cd' User entered '98.0'	System	22 Sep 2020 19:10:00
	System	22 Sep 2020 19:10:00

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:09:51', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '485b7904-98c5-4a07-9b0b-2c3252da88cd'	System	22 Sep 2020 19:10:00
User entered 'No (N)'	System	22 Sep 2020 19:10:00

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:09:54', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '485b7904-98c5-4a07-9b0b-2c3252da88cd' User entered '22 Sep 2020 13:09'	System	22 Sep 2020 19:10:00
	System	22 Sep 2020 19:10:00

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 7'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:00:38', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0047be6b-93b1-484a-b7b6-c9aa12d70cc3' User entered 'Yes (Y)'	System	24 Sep 2020 11:01:01
	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:00:42', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0047be6b-93b1-484a-b7b6-c9aa12d70cc3' User entered '97.3'	System	24 Sep 2020 11:01:01
	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:00:45', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0047be6b-93b1-484a-b7b6-c9aa12d70cc3'	System	24 Sep 2020 11:01:01
User entered 'Yes (Y)'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data to be updated as appropriate.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 08:50:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Ty Henry (b) (4)	24 Sep 2020 21:57:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:00:51', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0047be6b-93b1-484a-b7b6-c9aa12d70cc3'	(b) (4)	
User entered '1'	System	24 Sep 2020 11:01:01
	System	24 Sep 2020 11:01:01
	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:00:51', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0047be6b-93b1-484a-b7b6-c9aa12d70cc3' User entered '0'	System	24 Sep 2020 11:01:01
	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:00:54', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0047be6b-93b1-484a-b7b6-c9aa12d70cc3' User entered '24 Sep 2020 05:00'	System	24 Sep 2020 11:01:01
	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	24 Sep 2020 11:01:01
User entered 'Day 8'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:01', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e3a8b99d-3bc0-4e0a-a92a-c599c90eb5a5' User entered 'Yes (Y)'	System	25 Sep 2020 05:46:22
	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e3a8b99d-3bc0-4e0a-a92a-c599c90eb5a5' User entered '97.3'	System	25 Sep 2020 05:46:22
	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:10', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e3a8b99d-3bc0-4e0a-a92a-c599c90eb5a5'	System	25 Sep 2020 05:46:22
User entered 'Yes (Y)'	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data to be updated.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 12:04:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Ty Henry (b) (4)	05 Oct 2020 22:45:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:16', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e3a8b99d-3bc0-4e0a-a92a-c599c90eb5a5'	(b) (4)	
User entered '1'	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data to be updated.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 12:04:57
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:16', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e3a8b99d-3bc0-4e0a-a92a-c599c90eb5a5'	Ty Henry (b) (4) (b) (4)	05 Oct 2020 22:45:11
User entered '1'	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:18', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e3a8b99d-3bc0-4e0a-a92a-c599c90eb5a5' User entered '24 Sep 2020 23:46'	System	25 Sep 2020 05:46:22
	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	24 Sep 2020 11:01:01
User entered 'Day 9'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:00:45', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '40a83427-7419-4564-946b-95a7ff632cb1' User entered 'Yes (Y)'	System	25 Sep 2020 18:01:06
	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:00:50', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '40a83427-7419-4564-946b-95a7ff632cb1' User entered '97.9'	System	25 Sep 2020 18:01:06
	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:00:56', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '40a83427-7419-4564-946b-95a7ff632cb1'	System	25 Sep 2020 18:01:06
User entered 'Yes (Y)'	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data to be updated.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 12:05:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Ty Henry (b) (4)	05 Oct 2020 22:45:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:00:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '40a83427-7419-4564-946b-95a7ff632cb1'	(b) (4)	
User entered '1'	System	25 Sep 2020 18:01:06
	System	25 Sep 2020 18:01:06
	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:00:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '40a83427-7419-4564-946b-95a7ff632cb1' User entered '0'	System	25 Sep 2020 18:01:06
	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:02', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '40a83427-7419-4564-946b-95a7ff632cb1' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 18:01:06
	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	25 Sep 2020 05:46:22
User entered 'Day 10'	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:34:52', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3f21e72e-eef5-474b-8b59-83cdc697237b' User entered 'Yes (Y)'	System	27 Sep 2020 08:35:10
	System	27 Sep 2020 08:35:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:34:57', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3f21e72e-eef5-474b-8b59-83cdc697237b' User entered '96.2'	System	27 Sep 2020 08:35:10
	System	27 Sep 2020 08:35:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:01', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3f21e72e-eef5-474b-8b59-83cdc697237b' User entered 'Yes (Y)'	System	27 Sep 2020 08:35:10
	System	27 Sep 2020 08:35:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:05', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3f21e72e-eef5-474b-8b59-83cdc697237b' User entered '0'	System	27 Sep 2020 08:35:10
	System	27 Sep 2020 08:35:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data to be updated.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 12:05:09
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:05', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3f21e72e-eef5-474b-8b59-83cdc697237b' User entered '1'	Ty Henry (b) (4) (b) (4)	05 Oct 2020 22:45:32
	System	27 Sep 2020 08:35:10
	System	27 Sep 2020 08:35:10
	System	27 Sep 2020 08:35:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:07', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3f21e72e-eef5-474b-8b59-83cdc697237b' User entered '27 Sep 2020 02:35'	System	27 Sep 2020 08:35:10
	System	27 Sep 2020 08:35:10

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 05:46:22

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	25 Sep 2020 18:01:06
User entered 'Day 11'	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:21:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:08:20', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dc33bb72-9106-4af6-afca-af61798d854a' User entered 'Yes (Y)'	System	28 Sep 2020 16:08:36
	System	28 Sep 2020 16:08:36

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:21:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:08:24', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dc33bb72-9106-4af6-afca-af61798d854a' User entered '97.1'	System	28 Sep 2020 16:08:36
	System	28 Sep 2020 16:08:36

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:08:27', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dc33bb72-9106-4af6-afca-af61798d854a' User entered 'No (N)'	System	28 Sep 2020 16:08:36
	System	28 Sep 2020 16:08:36

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:08:29', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dc33bb72-9106-4af6-afca-af61798d854a' User entered '28 Sep 2020 10:08'	System	28 Sep 2020 16:08:36
	System	28 Sep 2020 16:08:36

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:20:44', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fc6e9284-384f-492b-9b3d-66b8a36c13d7'	System	17 Sep 2020 17:21:06
User entered 'None (1)'	System	17 Sep 2020 17:21:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:20:49', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fc6e9284-384f-492b-9b3d-66b8a36c13d7'	System	17 Sep 2020 17:21:06
User entered 'No (N)'	System	17 Sep 2020 17:21:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:20:52', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fc6e9284-384f-492b-9b3d-66b8a36c13d7'	System	17 Sep 2020 17:21:06
User entered 'No (N)'	System	17 Sep 2020 17:21:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:20:57', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fc6e9284-384f-492b-9b3d-66b8a36c13d7'	System	17 Sep 2020 17:21:06
User entered 'None (1)'	System	17 Sep 2020 17:21:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:21:03', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fc6e9284-384f-492b-9b3d-66b8a36c13d7'	System	17 Sep 2020 17:21:06
User entered '17 Sep 2020 11:21'	System	17 Sep 2020 17:21:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 11:08'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 13:38'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:18', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '20bb3900-7744-4fef-ab3d-f26c3d1e49e4'	System	18 Sep 2020 01:17:34
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 01:17:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:20', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '20bb3900-7744-4fef-ab3d-f26c3d1e49e4' User entered 'No (N)'	System	18 Sep 2020 01:17:34
	System	18 Sep 2020 01:17:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:23', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '20bb3900-7744-4fef-ab3d-f26c3d1e49e4' User entered 'No (N)'	System	18 Sep 2020 01:17:34
	System	18 Sep 2020 01:17:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:26', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '20bb3900-7744-4fef-ab3d-f26c3d1e49e4'	System	18 Sep 2020 01:17:34
User entered 'None (1)'	System	18 Sep 2020 01:17:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:28', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '20bb3900-7744-4fef-ab3d-f26c3d1e49e4'	System	18 Sep 2020 01:17:34
User entered '17 Sep 2020 19:17'	System	18 Sep 2020 01:17:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 14:33'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 2'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:34', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '703dd6d5-d95a-436d-943e-1aa09f55f00c'	System	18 Sep 2020 23:20:49
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		18 Sep 2020 23:20:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:37', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '703dd6d5-d95a-436d-943e-1aa09f55f00c' User entered 'No (N)'	System	18 Sep 2020 23:20:49
	System	18 Sep 2020 23:20:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:39', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '703dd6d5-d95a-436d-943e-1aa09f55f00c' User entered 'No (N)'	System	18 Sep 2020 23:20:49
	System	18 Sep 2020 23:20:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:42', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '703dd6d5-d95a-436d-943e-1aa09f55f00c'	System	18 Sep 2020 23:20:49
User entered 'None (1)'	System	18 Sep 2020 23:20:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:45', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '703dd6d5-d95a-436d-943e-1aa09f55f00c' User entered '18 Sep 2020 17:20'	System	18 Sep 2020 23:20:49
	System	18 Sep 2020 23:20:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 3'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fb747edf-9de3-44e9-8d86-8e5d705ac2de'	System	19 Sep 2020 21:00:20
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 21:00:20

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:09', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fb747edf-9de3-44e9-8d86-8e5d705ac2de'	System	19 Sep 2020 21:00:20
User entered 'No (N)'	System	19 Sep 2020 21:00:20

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:12', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fb747edf-9de3-44e9-8d86-8e5d705ac2de'	System	19 Sep 2020 21:00:20
User entered 'No (N)'	System	19 Sep 2020 21:00:20

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:15', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fb747edf-9de3-44e9-8d86-8e5d705ac2de'	System	19 Sep 2020 21:00:20
User entered 'None (1)'	System	19 Sep 2020 21:00:20

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:18', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fb747edf-9de3-44e9-8d86-8e5d705ac2de'	System	19 Sep 2020 21:00:20
User entered '19 Sep 2020 15:00'	System	19 Sep 2020 21:00:20

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 4'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:56:34', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'f6f3cf13-5566-4971-b40b-eac42460969c' User entered 'None (1)'	System	20 Sep 2020 22:56:49
	System	20 Sep 2020 22:56:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:56:38', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'f6f3cf13-5566-4971-b40b-eac42460969c' User entered 'No (N)'	System	20 Sep 2020 22:56:49
	System	20 Sep 2020 22:56:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:56:40', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'f6f3cf13-5566-4971-b40b-eac42460969c' User entered 'No (N)'	System	20 Sep 2020 22:56:49
	System	20 Sep 2020 22:56:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:56:42', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'f6f3cf13-5566-4971-b40b-eac42460969c'	System	20 Sep 2020 22:56:49
User entered 'None (1)'	System	20 Sep 2020 22:56:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:56:45', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'f6f3cf13-5566-4971-b40b-eac42460969c' User entered '20 Sep 2020 16:56'	System	20 Sep 2020 22:56:49
	System	20 Sep 2020 22:56:49

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 5'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:19', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd08b5831-f755-4bc4-a78d-d44c5ab602b0'	System	22 Sep 2020 02:07:34
User entered 'None (1)'	System	22 Sep 2020 02:07:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:22', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd08b5831-f755-4bc4-a78d-d44c5ab602b0' User entered 'No (N)'	System	22 Sep 2020 02:07:34
	System	22 Sep 2020 02:07:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:26', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd08b5831-f755-4bc4-a78d-d44c5ab602b0' User entered 'No (N)'	System	22 Sep 2020 02:07:34
	System	22 Sep 2020 02:07:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:29', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd08b5831-f755-4bc4-a78d-d44c5ab602b0' User entered 'None (1)'	System	22 Sep 2020 02:07:34
	System	22 Sep 2020 02:07:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:31', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd08b5831-f755-4bc4-a78d-d44c5ab602b0' User entered '21 Sep 2020 20:07'	System	22 Sep 2020 02:07:34
	System	22 Sep 2020 02:07:34

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 6'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:09:58', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '410f7953-8ac6-4b6f-bee1-5ee6d8f95c11'	System	22 Sep 2020 19:10:10
User entered 'None (1)'	System	22 Sep 2020 19:10:10

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '410f7953-8ac6-4b6f-bee1-5ee6d8f95c11' User entered 'No (N)'	System	22 Sep 2020 19:10:10
	System	22 Sep 2020 19:10:10

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:02', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '410f7953-8ac6-4b6f-bee1-5ee6d8f95c11' User entered 'No (N)'	System	22 Sep 2020 19:10:10
	System	22 Sep 2020 19:10:10

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:04', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '410f7953-8ac6-4b6f-bee1-5ee6d8f95c11'	System	22 Sep 2020 19:10:10
User entered 'None (1)'	System	22 Sep 2020 19:10:10

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:07', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '410f7953-8ac6-4b6f-bee1-5ee6d8f95c11'	System	22 Sep 2020 19:10:10
User entered '22 Sep 2020 13:10'	System	22 Sep 2020 19:10:10

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 7'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:00:58', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '61e45859-c3de-4465-9da7-cd648c4cc865'	System	24 Sep 2020 11:01:13
User entered 'None (1)'	System	24 Sep 2020 11:01:13

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '61e45859-c3de-4465-9da7-cd648c4cc865' User entered 'No (N)'	System	24 Sep 2020 11:01:13
	System	24 Sep 2020 11:01:13

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:01', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '61e45859-c3de-4465-9da7-cd648c4cc865'	System	24 Sep 2020 11:01:13
User entered 'No (N)'	System	24 Sep 2020 11:01:13

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:03', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '61e45859-c3de-4465-9da7-cd648c4cc865'	System	24 Sep 2020 11:01:13
User entered 'None (1)'	System	24 Sep 2020 11:01:13

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '61e45859-c3de-4465-9da7-cd648c4cc865' User entered '24 Sep 2020 05:01'	System	24 Sep 2020 11:01:13
	System	24 Sep 2020 11:01:13

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:23:20', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6819fc22-6614-47fc-9cce-85a051d76dde' User entered 'None (0)'	System	17 Sep 2020 17:23:51
	System	17 Sep 2020 17:23:51

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:23:24', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6819fc22-6614-47fc-9cce-85a051d76dde' User entered 'None (0)'	System	17 Sep 2020 17:23:51
	System	17 Sep 2020 17:23:51

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:23:29', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6819fc22-6614-47fc-9cce-85a051d76dde' User entered 'None (0)'	System	17 Sep 2020 17:23:51
	System	17 Sep 2020 17:23:51

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:23:32', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6819fc22-6614-47fc-9cce-85a051d76dde' User entered 'None (0)'	System	17 Sep 2020 17:23:51
	System	17 Sep 2020 17:23:51

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:23:34', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6819fc22-6614-47fc-9cce-85a051d76dde' User entered 'None (0)'	System	17 Sep 2020 17:23:51
	System	17 Sep 2020 17:23:51

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:23:40', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6819fc22-6614-47fc-9cce-85a051d76dde' User entered 'None (0)'	System	17 Sep 2020 17:23:51
	System	17 Sep 2020 17:23:51

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:23:43', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6819fc22-6614-47fc-9cce-85a051d76dde' User entered 'No (N)'	System	17 Sep 2020 17:23:51
	System	17 Sep 2020 17:23:51

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T11:23:46', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6819fc22-6614-47fc-9cce-85a051d76dde' User entered '17 Sep 2020 11:23'	System	17 Sep 2020 17:23:51
	System	17 Sep 2020 17:23:51

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 11:08'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 13:38'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:32', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ca27a5da-d1be-48d6-ab1e-e1f276716444' User entered 'None (0)'	System	18 Sep 2020 01:17:49
	System	18 Sep 2020 01:17:49

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:34', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ca27a5da-d1be-48d6-ab1e-e1f276716444' User entered 'None (0)'	System	18 Sep 2020 01:17:49
	System	18 Sep 2020 01:17:49

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:36', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ca27a5da-d1be-48d6-ab1e-e1f276716444' User entered 'None (0)'	System	18 Sep 2020 01:17:49
	System	18 Sep 2020 01:17:49

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:39', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ca27a5da-d1be-48d6-ab1e-e1f276716444' User entered 'None (0)'	System	18 Sep 2020 01:17:49
	System	18 Sep 2020 01:17:49

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:40', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ca27a5da-d1be-48d6-ab1e-e1f276716444' User entered 'None (0)'	System	18 Sep 2020 01:17:49
	System	18 Sep 2020 01:17:49

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:42', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ca27a5da-d1be-48d6-ab1e-e1f276716444' User entered 'None (0)'	System	18 Sep 2020 01:17:49
	System	18 Sep 2020 01:17:49

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:44', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ca27a5da-d1be-48d6-ab1e-e1f276716444'	System	18 Sep 2020 01:17:49
User entered 'No (N)'	System	18 Sep 2020 01:17:49

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-17T19:17:46', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ca27a5da-d1be-48d6-ab1e-e1f276716444'	System	18 Sep 2020 01:17:49
User entered '17 Sep 2020 19:17'	System	18 Sep 2020 01:17:49

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '17 Sep 2020 14:33'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 2'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:49', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '22bc4f32-f6bb-4054-bde6-1a4c393fb519' User entered 'None (0)'	System	18 Sep 2020 23:21:11
	System	18 Sep 2020 23:21:11

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:52', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '22bc4f32-f6bb-4054-bde6-1a4c393fb519' User entered 'None (0)'	System	18 Sep 2020 23:21:11
	System	18 Sep 2020 23:21:11

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:20:58', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '22bc4f32-f6bb-4054-bde6-1a4c393fb519'	System	18 Sep 2020 23:21:11
User entered 'Some interference with activity (2)'	System	18 Sep 2020 23:21:11

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:21:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '22bc4f32-f6bb-4054-bde6-1a4c393fb519' User entered 'None (0)'	System	18 Sep 2020 23:21:11
	System	18 Sep 2020 23:21:11

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:21:02', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '22bc4f32-f6bb-4054-bde6-1a4c393fb519' User entered 'None (0)'	System	18 Sep 2020 23:21:11
	System	18 Sep 2020 23:21:11

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:21:04', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '22bc4f32-f6bb-4054-bde6-1a4c393fb519' User entered 'None (0)'	System	18 Sep 2020 23:21:11
	System	18 Sep 2020 23:21:11

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:21:07', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '22bc4f32-f6bb-4054-bde6-1a4c393fb519' User entered 'No (N)'	System	18 Sep 2020 23:21:11
	System	18 Sep 2020 23:21:11

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-18T17:21:09', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '22bc4f32-f6bb-4054-bde6-1a4c393fb519'	System	18 Sep 2020 23:21:11
User entered '18 Sep 2020 17:21'	System	18 Sep 2020 23:21:11

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 3'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:22', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6062b4ab-fdd2-4381-ade4-e55dcc534199' User entered 'None (0)'	System	19 Sep 2020 21:00:41
	System	19 Sep 2020 21:00:41

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:25', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6062b4ab-fdd2-4381-ade4-e55dcc534199' User entered 'None (0)'	System	19 Sep 2020 21:00:41
	System	19 Sep 2020 21:00:41

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:27', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6062b4ab-fdd2-4381-ade4-e55dcc534199' User entered 'None (0)'	System	19 Sep 2020 21:00:41
	System	19 Sep 2020 21:00:41

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:30', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6062b4ab-fdd2-4381-ade4-e55dcc534199' User entered 'None (0)'	System	19 Sep 2020 21:00:41
	System	19 Sep 2020 21:00:41

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:32', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6062b4ab-fdd2-4381-ade4-e55dcc534199' User entered 'None (0)'	System	19 Sep 2020 21:00:41
	System	19 Sep 2020 21:00:41

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:34', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6062b4ab-fdd2-4381-ade4-e55dcc534199' User entered 'None (0)'	System	19 Sep 2020 21:00:41
	System	19 Sep 2020 21:00:41

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:37', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6062b4ab-fdd2-4381-ade4-e55dcc534199'	System	19 Sep 2020 21:00:41
User entered 'No (N)'	System	19 Sep 2020 21:00:41

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-19T15:00:39', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6062b4ab-fdd2-4381-ade4-e55dcc534199'	System	19 Sep 2020 21:00:41
User entered '19 Sep 2020 15:00'	System	19 Sep 2020 21:00:41

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 4'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:58:03', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0b820608-3ea9-450f-a074-aad13fdcf607' User entered 'None (0)'	System	20 Sep 2020 22:58:21
	System	20 Sep 2020 22:58:21

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:58:04', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0b820608-3ea9-450f-a074-aad13fdcf607' User entered 'None (0)'	System	20 Sep 2020 22:58:21
	System	20 Sep 2020 22:58:21

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:58:07', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0b820608-3ea9-450f-a074-aad13fdcf607' User entered 'None (0)'	System	20 Sep 2020 22:58:21
	System	20 Sep 2020 22:58:21

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:58:10', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0b820608-3ea9-450f-a074-aad13fdcf607' User entered 'None (0)'	System	20 Sep 2020 22:58:21
	System	20 Sep 2020 22:58:21

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:58:12', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0b820608-3ea9-450f-a074-aad13fdcf607' User entered 'None (0)'	System	20 Sep 2020 22:58:21
	System	20 Sep 2020 22:58:21

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:58:14', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0b820608-3ea9-450f-a074-aad13fdcf607' User entered 'None (0)'	System	20 Sep 2020 22:58:21
	System	20 Sep 2020 22:58:21

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:58:17', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0b820608-3ea9-450f-a074-aad13fdcf607' User entered 'No (N)'	System	20 Sep 2020 22:58:21
	System	20 Sep 2020 22:58:21

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-20T16:58:20', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0b820608-3ea9-450f-a074-aad13fdcf607' User entered '20 Sep 2020 16:58'	System	20 Sep 2020 22:58:21
	System	20 Sep 2020 22:58:21

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 5'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:37', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd8f22b56-5adf-4929-b086-aa01b4d0280b' User entered 'None (0)'	System	22 Sep 2020 02:08:34
	System	22 Sep 2020 02:08:34

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:07:39', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd8f22b56-5adf-4929-b086-aa01b4d0280b' User entered 'None (0)'	System	22 Sep 2020 02:08:34
	System	22 Sep 2020 02:08:34

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:08:10', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd8f22b56-5adf-4929-b086-aa01b4d0280b' User entered 'None (0)'	System	22 Sep 2020 02:08:34
	System	22 Sep 2020 02:08:34

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:08:22', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd8f22b56-5adf-4929-b086-aa01b4d0280b' User entered 'None (0)'	System	22 Sep 2020 02:08:34
	System	22 Sep 2020 02:08:34

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:08:24', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd8f22b56-5adf-4929-b086-aa01b4d0280b' User entered 'None (0)'	System	22 Sep 2020 02:08:34
	System	22 Sep 2020 02:08:34

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:08:26', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd8f22b56-5adf-4929-b086-aa01b4d0280b' User entered 'None (0)'	System	22 Sep 2020 02:08:34
	System	22 Sep 2020 02:08:34

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:08:28', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd8f22b56-5adf-4929-b086-aa01b4d0280b' User entered 'No (N)'	System	22 Sep 2020 02:08:34
	System	22 Sep 2020 02:08:34

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-21T20:08:30', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd8f22b56-5adf-4929-b086-aa01b4d0280b' User entered '21 Sep 2020 20:08'	System	22 Sep 2020 02:08:34
	System	22 Sep 2020 02:08:34

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 6'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:10', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dad4446e-e614-47dd-97c5-7dfbeb58c5bc' User entered 'None (0)'	System	22 Sep 2020 19:10:30
	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:14', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dad4446e-e614-47dd-97c5-7dfbeb58c5bc'	System	22 Sep 2020 19:10:30
User entered 'No interference with activity (1)'	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:16', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dad4446e-e614-47dd-97c5-7dfbeb58c5bc' User entered 'None (0)'	System	22 Sep 2020 19:10:30
	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:18', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dad4446e-e614-47dd-97c5-7dfbeb58c5bc' User entered 'None (0)'	System	22 Sep 2020 19:10:30
	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:20', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dad4446e-e614-47dd-97c5-7dfbeb58c5bc' User entered 'None (0)'	System	22 Sep 2020 19:10:30
	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:21', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dad4446e-e614-47dd-97c5-7dfbeb58c5bc' User entered 'None (0)'	System	22 Sep 2020 19:10:30
	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:24', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dad4446e-e614-47dd-97c5-7dfbeb58c5bc' User entered 'No (N)'	System	22 Sep 2020 19:10:30
	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-22T13:10:27', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'dad4446e-e614-47dd-97c5-7dfbeb58c5bc' User entered '22 Sep 2020 13:10'	System	22 Sep 2020 19:10:30
	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 7'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:10', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8ae33203-9bd7-497e-9076-26b65d2cbd51' User entered 'None (0)'	System	24 Sep 2020 11:01:40
	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:16', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8ae33203-9bd7-497e-9076-26b65d2cbd51'	System	24 Sep 2020 11:01:40
User entered 'Some interference with activity (2)'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:18', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8ae33203-9bd7-497e-9076-26b65d2cbd51'	System	24 Sep 2020 11:01:40
User entered 'Some interference with activity (2)'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:22', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8ae33203-9bd7-497e-9076-26b65d2cbd51' User entered 'None (0)'	System	24 Sep 2020 11:01:40
	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:25', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8ae33203-9bd7-497e-9076-26b65d2cbd51'	System	24 Sep 2020 11:01:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:29', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8ae33203-9bd7-497e-9076-26b65d2cbd51' User entered 'None (0)'	System	24 Sep 2020 11:01:40
	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:32', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8ae33203-9bd7-497e-9076-26b65d2cbd51' User entered 'No (N)'	System	24 Sep 2020 11:01:40
	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T05:01:34', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8ae33203-9bd7-497e-9076-26b65d2cbd51' User entered '24 Sep 2020 05:01'	System	24 Sep 2020 11:01:40
	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	22 Sep 2020 19:10:30
User entered 'Day 8'	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:45:52', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'bc08260a-9753-4d0c-87a4-48defafe42eb' User entered 'Significant; prevents daily activity (3)'	System	25 Sep 2020 05:45:58

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:45:55', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'bc08260a-9753-4d0c-87a4-48defafe42eb' User entered '24 Sep 2020 23:45'	System	25 Sep 2020 05:45:58
	System	25 Sep 2020 05:45:58

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	24 Sep 2020 11:01:40
User entered 'Day 9'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:08', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e16e1384-25fc-462f-b578-71272fb45528'	System	25 Sep 2020 18:01:16
User entered 'Significant; prevents daily activity (3)'	System	25 Sep 2020 18:01:16

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:10', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e16e1384-25fc-462f-b578-71272fb45528' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 18:01:16
	System	25 Sep 2020 18:01:16

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	25 Sep 2020 05:45:58
User entered 'Day 10'	System	25 Sep 2020 05:45:58

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:13', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'a8db5acd-5e31-487c-9303-0f26c2979a76'	System	27 Sep 2020 08:35:18
User entered 'Some interference with activity (2)'	System	27 Sep 2020 08:35:18

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:15', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'a8db5acd-5e31-487c-9303-0f26c2979a76'	System	27 Sep 2020 08:35:18
User entered '27 Sep 2020 02:35'	System	27 Sep 2020 08:35:18

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 05:45:58

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 05:45:58

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	25 Sep 2020 18:01:16
User entered 'Day 11'	System	25 Sep 2020 18:01:16

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:09:39', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '39fc2543-850d-4e19-a6b9-e4cffc5b0f58'	System	28 Sep 2020 16:09:46
User entered 'Some interference with activity (2)'	System	28 Sep 2020 16:09:46

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:09:41', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '39fc2543-850d-4e19-a6b9-e4cffc5b0f58'	System	28 Sep 2020 16:09:46
User entered '28 Sep 2020 10:09'	System	28 Sep 2020 16:09:46

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:01:16

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:01:16

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	27 Sep 2020 08:35:18
User entered 'Day 12'	System	27 Sep 2020 08:35:18

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-29T08:50:04', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8306c2d0-3a73-426d-8770-8d862258ba33'	System	29 Sep 2020 14:50:09
User entered 'Significant; prevents daily activity (3)'	System	29 Sep 2020 14:50:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-29T08:50:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8306c2d0-3a73-426d-8770-8d862258ba33'	System	29 Sep 2020 14:50:09
User entered '29 Sep 2020 08:50'	System	29 Sep 2020 14:50:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 08:35:18

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 08:35:18

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	28 Sep 2020 16:09:46
User entered 'Day 13'	System	28 Sep 2020 16:09:46

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-29T16:24:08', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c812af11-e73e-4349-8386-005f5cd077d0'	System	29 Sep 2020 22:24:36
User entered 'Significant; prevents daily activity (3)'	System	29 Sep 2020 22:24:36

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-29T16:24:13', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c812af11-e73e-4349-8386-005f5cd077d0' User entered '29 Sep 2020 16:24'	System	29 Sep 2020 22:24:36
	System	29 Sep 2020 22:24:36

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:09:46

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:09:46

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	29 Sep 2020 14:50:09
User entered 'Day 14'	System	29 Sep 2020 14:50:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-30T13:21:24', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e69859a4-5c34-4b7b-b2bd-41be2f9e665c' User entered 'Some interference with activity (2)'	System	30 Sep 2020 19:21:30
	System	30 Sep 2020 19:21:30

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-30T13:21:27', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e69859a4-5c34-4b7b-b2bd-41be2f9e665c' User entered '30 Sep 2020 13:21'	System	30 Sep 2020 19:21:30
	System	30 Sep 2020 19:21:30

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:50:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:50:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	29 Sep 2020 22:24:36
User entered 'Day 15'	System	29 Sep 2020 22:24:36

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-01T12:59:23', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '21182231-3ef9-4614-9c6c-91f601ed22d8'	System	01 Oct 2020 18:59:28
User entered 'Some interference with activity (2)'	System	01 Oct 2020 18:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-01T12:59:25', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '21182231-3ef9-4614-9c6c-91f601ed22d8' User entered '01 Oct 2020 12:59'	System	01 Oct 2020 18:59:28
	System	01 Oct 2020 18:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 22:24:36

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 22:24:36

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	30 Sep 2020 19:21:30
User entered 'Day 16'	System	30 Sep 2020 19:21:30

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-02T17:16:35', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2ccc5108-aeeb-439a-8058-76bfefff24a9'	System	02 Oct 2020 23:16:41
User entered 'Some interference with activity (2)'	System	02 Oct 2020 23:16:41

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-02T17:16:38', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2ccc5108-aeeb-439a-8058-76bfefff24a9' User entered '02 Oct 2020 17:16'	System	02 Oct 2020 23:16:41
	System	02 Oct 2020 23:16:41

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:21:30

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:21:30

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	01 Oct 2020 18:59:28
User entered 'Day 17'	System	01 Oct 2020 18:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-03T12:25:52', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8004b099-8471-4032-b7a0-682bd611843a'	System	03 Oct 2020 18:25:57
User entered 'Some interference with activity (2)'	System	03 Oct 2020 18:25:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-03T12:25:56', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '8004b099-8471-4032-b7a0-682bd611843a' User entered '03 Oct 2020 12:25'	System	03 Oct 2020 18:25:57
	System	03 Oct 2020 18:25:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	02 Oct 2020 23:16:41
User entered 'Day 18'	System	02 Oct 2020 23:16:41

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-04T23:59:17', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '44e9e35e-d193-4016-b635-a2da6b22b80e'	System	05 Oct 2020 05:59:23
User entered 'Some interference with activity (2)'	System	05 Oct 2020 05:59:23

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-04T23:59:19', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '44e9e35e-d193-4016-b635-a2da6b22b80e' User entered '04 Oct 2020 23:59'	System	05 Oct 2020 05:59:23
	System	05 Oct 2020 05:59:23

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 23:16:41

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 23:16:41

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	03 Oct 2020 18:25:57
User entered 'Day 19'	System	03 Oct 2020 18:25:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-05T13:35:08', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'da768683-6630-4dc9-aeaa-6bc4c03b0451'	System	05 Oct 2020 19:35:13
User entered 'No interference with activity (1)'	System	05 Oct 2020 19:35:13

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-05T13:35:09', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'da768683-6630-4dc9-aeaa-6bc4c03b0451' User entered '05 Oct 2020 13:35'	System	05 Oct 2020 19:35:13
	System	05 Oct 2020 19:35:13

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 18:25:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 18:25:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	05 Oct 2020 05:59:23
User entered 'Day 20'	System	05 Oct 2020 05:59:23

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-06T15:42:49', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fa1372a5-74bb-4aa3-9404-f4c4b84ede03'	System	06 Oct 2020 21:42:53
User entered 'No interference with activity (1)'	System	06 Oct 2020 21:42:53

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-06T15:42:50', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fa1372a5-74bb-4aa3-9404-f4c4b84ede03' User entered '06 Oct 2020 15:42'	System	06 Oct 2020 21:42:53
	System	06 Oct 2020 21:42:53

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 05:59:23

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 05:59:23

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	05 Oct 2020 19:35:13
User entered 'Day 21'	System	05 Oct 2020 19:35:13

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-07T16:30:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e43d35e2-ed3e-4f43-b1c2-8fb17d23cf0a'	System	07 Oct 2020 22:30:09
User entered 'No interference with activity (1)'	System	07 Oct 2020 22:30:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-07T16:30:08', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e43d35e2-ed3e-4f43-b1c2-8fb17d23cf0a' User entered '07 Oct 2020 16:30'	System	07 Oct 2020 22:30:09
	System	07 Oct 2020 22:30:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 19:35:13

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 19:35:13

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	06 Oct 2020 21:42:53
User entered 'Day 22'	System	06 Oct 2020 21:42:53

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 21:42:53

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 21:42:53

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	07 Oct 2020 22:30:09
User entered 'Day 23'	System	07 Oct 2020 22:30:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-09T17:22:53', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '93679f44-dc51-4033-aac3-a522d23b0af3'	System	09 Oct 2020 23:22:57
User entered 'Some interference with activity (2)'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-09T17:22:55', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '93679f44-dc51-4033-aac3-a522d23b0af3' User entered '09 Oct 2020 17:22'	System	09 Oct 2020 23:22:57
	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:30:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:30:09

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	09 Oct 2020 23:22:57
User entered 'Day 24'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	09 Oct 2020 23:22:57
User entered 'Day 25'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 11 Aug 2021 22:21:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	24 Sep 2020 11:01:40
User entered 'Day 8'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:23', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd5f8d01f-1128-422e-aad0-5ce2eb2997ff' User entered 'Significant; prevents daily activity (3)'	System	25 Sep 2020 05:46:29

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:27', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd5f8d01f-1128-422e-aad0-5ce2eb2997ff' User entered '24 Sep 2020 23:46'	System	25 Sep 2020 05:46:29
	System	25 Sep 2020 05:46:29

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	24 Sep 2020 11:01:40
User entered 'Day 9'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:19', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c5998270-15b4-4ec4-b9c8-d60649b518b8'	System	25 Sep 2020 18:01:24
User entered 'Some interference with activity (2)'	System	25 Sep 2020 18:01:24

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:21', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c5998270-15b4-4ec4-b9c8-d60649b518b8'	System	25 Sep 2020 18:01:24
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 18:01:24

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	25 Sep 2020 05:46:29
User entered 'Day 10'	System	25 Sep 2020 05:46:29

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:18', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6e54a20b-d721-4b4d-9fb1-ed6b75058471'	System	27 Sep 2020 08:35:24
User entered 'No interference with activity (1)'	System	27 Sep 2020 08:35:24

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:21', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6e54a20b-d721-4b4d-9fb1-ed6b75058471' User entered '27 Sep 2020 02:35'	System	27 Sep 2020 08:35:24
	System	27 Sep 2020 08:35:24

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 05:46:29

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 05:46:29

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	25 Sep 2020 18:01:24
User entered 'Day 11'	System	25 Sep 2020 18:01:24

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:09:45', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'a4a25d00-3c0e-48dd-b7e2-f40d2199af81' User entered 'None (0)'	System	28 Sep 2020 16:09:52
	System	28 Sep 2020 16:09:52

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:09:49', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'a4a25d00-3c0e-48dd-b7e2-f40d2199af81' User entered '28 Sep 2020 10:09'	System	28 Sep 2020 16:09:52
	System	28 Sep 2020 16:09:52

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:01:24

US3332089

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:01:24

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	24 Sep 2020 11:01:40
User entered 'Day 8'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:46:36', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '96d669c2-6db5-40e6-a05e-9862b30ba780'	System	25 Sep 2020 05:47:25
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Sep 2020 05:47:25

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:47:21', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '96d669c2-6db5-40e6-a05e-9862b30ba780' User entered '24 Sep 2020 23:47'	System	25 Sep 2020 05:47:25
	System	25 Sep 2020 05:47:25

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	24 Sep 2020 11:01:40
User entered 'Day 9'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 11 Aug 2021 22:21:48

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:24', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'a5e93f71-6d4e-437e-a69d-4c4ff00197dd' User entered 'None (0)'	System	25 Sep 2020 18:01:31
	System	25 Sep 2020 18:01:31

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:27', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'a5e93f71-6d4e-437e-a69d-4c4ff00197dd' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 18:01:31
	System	25 Sep 2020 18:01:31

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:01:40

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	22 Sep 2020 19:10:30
User entered 'Day 8'	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:47:40', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '107115c5-0239-4005-9900-51f82bc71aaa' User entered 'No (N)'	System	25 Sep 2020 05:47:46
	System	25 Sep 2020 05:47:46

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-24T23:47:44', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '107115c5-0239-4005-9900-51f82bc71aaa' User entered '24 Sep 2020 23:47'	System	25 Sep 2020 05:47:46
	System	25 Sep 2020 05:47:46

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 19:10:30

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	24 Sep 2020 11:01:01
User entered 'Day 9'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:32', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '033b3fba-a60e-491f-900e-c378550b7b81' User entered 'No (N)'	System	25 Sep 2020 18:01:37
	System	25 Sep 2020 18:01:37

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-25T12:01:35', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '033b3fba-a60e-491f-900e-c378550b7b81' User entered '25 Sep 2020 12:01'	System	25 Sep 2020 18:01:37
	System	25 Sep 2020 18:01:37

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 11:01:01

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	25 Sep 2020 05:45:58
User entered 'Day 10'	System	25 Sep 2020 05:45:58

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:25', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ce237cf8-d69e-4eda-b196-9eb8cb35f9ca' User entered 'No (N)'	System	27 Sep 2020 08:35:29
	System	27 Sep 2020 08:35:29

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-27T02:35:27', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'ce237cf8-d69e-4eda-b196-9eb8cb35f9ca' User entered '27 Sep 2020 02:35'	System	27 Sep 2020 08:35:29
	System	27 Sep 2020 08:35:29

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 05:45:58

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 05:45:58

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	25 Sep 2020 18:01:06
User entered 'Day 11'	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:09:53', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '549de83d-d102-45f0-928f-76ff6be45c2c'	System	28 Sep 2020 16:09:58
User entered 'No (N)'	System	28 Sep 2020 16:09:58

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-28T10:09:55', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '549de83d-d102-45f0-928f-76ff6be45c2c' User entered '28 Sep 2020 10:09'	System	28 Sep 2020 16:09:58
	System	28 Sep 2020 16:09:58

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 18:01:06

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	28 Sep 2020 16:09:46
User entered 'Day 13'	System	28 Sep 2020 16:09:46

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-29T16:24:18', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fbedee46-8ba5-4c82-9075-76ac1524524c' User entered 'No (N)'	System	29 Sep 2020 22:24:38
	System	29 Sep 2020 22:24:38

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-29T16:24:21', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'fbedee46-8ba5-4c82-9075-76ac1524524c' User entered '29 Sep 2020 16:24'	System	29 Sep 2020 22:24:38
	System	29 Sep 2020 22:24:38

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:09:46

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:09:46

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	29 Sep 2020 14:50:09
User entered 'Day 14'	System	29 Sep 2020 14:50:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-30T13:21:31', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0589abf4-112f-4664-9c92-e83ee3fbb3fe' User entered 'No (N)'	System	30 Sep 2020 19:21:45
	System	30 Sep 2020 19:21:45

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-09-30T13:21:42', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '0589abf4-112f-4664-9c92-e83ee3fbb3fe' User entered '30 Sep 2020 13:21'	System	30 Sep 2020 19:21:45
	System	30 Sep 2020 19:21:45

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:50:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:50:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	29 Sep 2020 22:24:36
User entered 'Day 15'	System	29 Sep 2020 22:24:36

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-01T12:59:29', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'b6295093-394b-437b-b9bd-2054aa00dc54'	System	01 Oct 2020 18:59:36
User entered 'No (N)'	System	01 Oct 2020 18:59:36

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-01T12:59:32', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'b6295093-394b-437b-b9bd-2054aa00dc54' User entered '01 Oct 2020 12:59'	System	01 Oct 2020 18:59:36
	System	01 Oct 2020 18:59:36

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 22:24:36

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 22:24:36

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	30 Sep 2020 19:21:30
User entered 'Day 16'	System	30 Sep 2020 19:21:30

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-02T17:16:41', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c0e605d1-eeeb-4cde-8d08-f8d659b6a872' User entered 'No (N)'	System	02 Oct 2020 23:16:44
	System	02 Oct 2020 23:16:44

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-02T17:16:43', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c0e605d1-eeeb-4cde-8d08-f8d659b6a872'	System	02 Oct 2020 23:16:44
User entered '02 Oct 2020 17:16'	System	02 Oct 2020 23:16:44

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 19:21:30

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 19:21:30

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	01 Oct 2020 18:59:28
User entered 'Day 17'	System	01 Oct 2020 18:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-03T12:25:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6dcbc1c2-dfa0-46d4-9bb7-9a1c0ab2ebb3' User entered 'No (N)'	System	03 Oct 2020 18:26:09
	System	03 Oct 2020 18:26:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-03T12:26:02', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '6dcbc1c2-dfa0-46d4-9bb7-9a1c0ab2ebb3' User entered '03 Oct 2020 12:26'	System	03 Oct 2020 18:26:09
	System	03 Oct 2020 18:26:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 18:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 18:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	02 Oct 2020 23:16:41
User entered 'Day 18'	System	02 Oct 2020 23:16:41

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-04T23:59:23', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '088fad79-baec-4146-8114-94d165cedd08' User entered 'No (N)'	System	05 Oct 2020 05:59:28
	System	05 Oct 2020 05:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-04T23:59:26', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '088fad79-baec-4146-8114-94d165cedd08' User entered '04 Oct 2020 23:59'	System	05 Oct 2020 05:59:28
	System	05 Oct 2020 05:59:28

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 23:16:41

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 23:16:41

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	03 Oct 2020 18:25:57
User entered 'Day 19'	System	03 Oct 2020 18:25:57

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-05T13:35:14', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3ad2775e-970a-47e3-8025-3e3912e1d34d' User entered 'No (N)'	System	05 Oct 2020 19:35:19
	System	05 Oct 2020 19:35:19

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-05T13:35:16', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3ad2775e-970a-47e3-8025-3e3912e1d34d' User entered '05 Oct 2020 13:35'	System	05 Oct 2020 19:35:19
	System	05 Oct 2020 19:35:19

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 18:25:57

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 18:25:57

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	05 Oct 2020 05:59:23
User entered 'Day 20'	System	05 Oct 2020 05:59:23

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-06T15:42:54', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '30a28f19-0731-44f5-8eac-232c9cf2bc91' User entered 'No (N)'	System	06 Oct 2020 21:42:59
	System	06 Oct 2020 21:42:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-06T15:42:56', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '30a28f19-0731-44f5-8eac-232c9cf2bc91' User entered '06 Oct 2020 15:42'	System	06 Oct 2020 21:42:59
	System	06 Oct 2020 21:42:59

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 05:59:23

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 05:59:23

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	05 Oct 2020 19:35:13
User entered 'Day 21'	System	05 Oct 2020 19:35:13

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-07T16:30:12', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '94d38d69-8459-4b10-b376-9549728eaf04'	System	07 Oct 2020 22:30:15
User entered 'No (N)'	System	07 Oct 2020 22:30:15

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-07T16:30:14', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '94d38d69-8459-4b10-b376-9549728eaf04' User entered '07 Oct 2020 16:30'	System	07 Oct 2020 22:30:15
	System	07 Oct 2020 22:30:15

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 19:35:13

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 19:35:13

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	06 Oct 2020 21:42:53
User entered 'Day 22'	System	06 Oct 2020 21:42:53

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 21:42:53

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 21:42:53

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	07 Oct 2020 22:30:09
User entered 'Day 23'	System	07 Oct 2020 22:30:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-09T17:22:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '68a29ad9-fd5c-4dac-a362-894cdf4d2275'	System	09 Oct 2020 23:23:09
User entered 'No (N)'	System	09 Oct 2020 23:23:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-10-09T17:23:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '68a29ad9-fd5c-4dac-a362-894cdf4d2275' User entered '09 Oct 2020 17:23'	System	09 Oct 2020 23:23:09
	System	09 Oct 2020 23:23:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:30:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:30:09

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	09 Oct 2020 23:22:57
User entered 'Day 24'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
Data entry locked.	System	09 Oct 2020 23:22:57
User entered 'Day 25'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:21:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:21:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 23:22:57

US3332089

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 11 Aug 2021 22:21:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:14:43
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 23:22:57

US3332089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:47:54
User entered 'Yes (Y)'	Colby Bostock (b) (4)	01 Oct 2020 19:55:54

US3332089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User closed query 'Per CDM- Safety Call Day 8 Visit date recorded as 25 SEP2020 Is same as Illness Visit Day 1 visit date 25 SEP2020. Kindly consider to verify and update data appropriately else please clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:13:18
Query 'Per CDM- Safety Call Day 8 Visit date recorded as 25 SEP2020 Is same as Illness Visit Day 1 visit date 25 SEP2020. Kindly consider to verify and update data appropriately else please clarify. Thank you. ' answered with 'Information is correct. Subject's safety call was when the illness visit was schedule for the same day. ' (Site from DM).	Kenadie Hamblin (b) (4) (b) (4)	06 Apr 2021 19:49:11
User opened query 'Per CDM- Safety Call Day 8 Visit date recorded as 25 SEP2020 Is same as Illness Visit Day 1 visit date 25 SEP2020. Kindly consider to verify and update data appropriately else please clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:12:44
User signature succeeded.	James Peterson (b) (4) (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:47:56
User entered '25 Sep 2020'	Colby Bostock (b) (4) (b) (4)	01 Oct 2020 19:55:54

US3332089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:47:58
User entered 'Contact Made (CONTACT MADE)'	Colby Bostock (b) (4)	01 Oct 2020 19:55:54

US3332089

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:00:03
User entered empty.	Colby Bostock (b) (4)	01 Oct 2020 19:55:54

US3332089

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:48:05
User entered 'Yes (Y)'	Colby Bostock (b) (4)	01 Oct 2020 19:56:01

US3332089

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'I'	System	01 Oct 2020 19:56:01

US3332089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:48:33
User entered 'Yes (Y)'	Colby Bostock (b) (4)	01 Oct 2020 19:56:30

US3332089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:01:20
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:06
User entered '01 Oct 2020' reason for change: Data Entry Error		10 Nov 2020 16:40:06
DataPoint Verified.		30 Oct 2020 20:48:35
User entered '1 Oct 2020'	Colby Bostock (b) (4)	01 Oct 2020 19:56:30
	(b) (4)	

US3332089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:48:36
User entered 'Contact Made (CONTACT MADE)'	Colby Bostock (b) (4) (b) (4)	01 Oct 2020 19:56:30

US3332089

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:00:13
User entered empty.	Colby Bostock (b) (4)	01 Oct 2020 19:56:30

US3332089

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:49:08
User entered 'Yes (Y)'	Colby Bostock (b) (4) (b) (4)	01 Oct 2020 19:56:34

US3332089

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'I'	System	01 Oct 2020 19:56:34

US3332089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:55:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:48:48

US3332089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:55:02
User entered '10 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 18:48:48

US3332089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:55:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 18:48:48

US3332089

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:55:02
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:48:48

US3332089

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 18:55:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:48:54

US3332089

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:38:12
User entered 'I'	System	05 Nov 2020 18:48:54

US3332089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:01:47
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:33

US3332089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:01:47
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:33

US3332089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[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 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:01:47
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:33

US3332089

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered 'VISIT2'	System	05 Jan 2021 20:05:33

US3332089

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:01:53
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 05:55:56

US3332089

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered 'I'	System	09 Jan 2021 05:55:56

US3332089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:05
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:16:48

US3332089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:05
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:16:48

US3332089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:05
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:16:48

US3332089

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:05
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'Not done. Visit two not completed per sponsor.'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:16:48

US3332089

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:10
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:16:52

US3332089

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered 'I'	System	14 Jan 2021 16:16:52

US3332089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:25
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:23

US3332089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:25
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:23

US3332089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:25
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:23

US3332089

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:25
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'Not done. Visit two not completed per sponsor.'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:23

US3332089

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:31
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:28

US3332089

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered 'I'	System	14 Jan 2021 16:17:28

US3332089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:40
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:53

US3332089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:40
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:53

US3332089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:40
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:53

US3332089

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:40
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'Not done. Visit two not completed per sponsor.'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:53

US3332089

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:40:44
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:17:57

US3332089

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered 'I'	System	14 Jan 2021 16:17:57

US3332089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:24
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:24

US3332089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:24
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:24

US3332089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[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 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:24
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:24

US3332089

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered 'VISIT3'	System	14 Jan 2021 16:18:24

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered empty.	System	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered empty.	System	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered empty.	System	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered empty.	System	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:30
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered empty.	System	14 Jan 2021 16:18:36

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38

US3332089

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38

US3332089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:37
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:52

US3332089

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:37
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:52

US3332089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:43
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:57

US3332089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:43
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:57

US3332089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:43
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:37:59
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:57

US3332089

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered empty.	System	14 Jan 2021 16:18:57

US3332089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:39:47
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:36:43
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:18:44

US3332089

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered '1'	System	14 Jan 2021 16:18:44

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37
Data entry locked.	System	17 Sep 2020 17:14:06
User entered 'Day 64'	System	17 Sep 2020 17:14:06

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Have you been exposed to someone with 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 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Please 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 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Please 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 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Please 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 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37
Data entry locked.	System	17 Sep 2020 17:14:06
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 17:14:06

US3332089

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 09:15:37
Data entry locked.	System	17 Sep 2020 17:14:06
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 17:14:06

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-12-05T06:25:42', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '77c6f128-4e96-4d64-ac02-39937c28d08b' User entered 'No (N)'	System	05 Dec 2020 13:26:13
	System	05 Dec 2020 13:26:13

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-12-05T06:26:05', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '77c6f128-4e96-4d64-ac02-39937c28d08b' User entered 'No (N)'	System	05 Dec 2020 13:26:13
	System	05 Dec 2020 13:26:13

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2020-12-05T06:26:09', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '77c6f128-4e96-4d64-ac02-39937c28d08b' User entered '05 Dec 2020 06:26:09'	System	05 Dec 2020 13:26:13
	System	05 Dec 2020 13:26:13

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-09T10:13:51', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e84088c5-3f70-4809-b0aa-19bfe3bc27e6'	System	09 Jan 2021 17:14:27
User entered 'No (N)'	System	09 Jan 2021 17:14:27

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-09T10:14:18', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e84088c5-3f70-4809-b0aa-19bfe3bc27e6'	System	09 Jan 2021 17:14:27
User entered 'No (N)'	System	09 Jan 2021 17:14:27

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-09T10:14:22', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'e84088c5-3f70-4809-b0aa-19bfe3bc27e6' User entered '09 Jan 2021 10:14:22'	System	09 Jan 2021 17:14:27
	System	09 Jan 2021 17:14:27

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-19T06:20:34', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '09d4ce7e-d96d-42f5-aac4-68a604efa023'	System	19 Jan 2021 13:21:11
User entered 'Yes (Y)'	System	19 Jan 2021 13:21:11

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-19T06:20:50', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '09d4ce7e-d96d-42f5-aac4-68a604efa023'	System	19 Jan 2021 13:21:11
User entered 'No (N)'	System	19 Jan 2021 13:21:11

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-19T06:20:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '09d4ce7e-d96d-42f5-aac4-68a604efa023'	System	19 Jan 2021 13:21:11
User entered 'No (N)'	System	19 Jan 2021 13:21:11

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-19T06:21:03', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '09d4ce7e-d96d-42f5-aac4-68a604efa023'	System	19 Jan 2021 13:21:11
User entered 'No (N)'	System	19 Jan 2021 13:21:11

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-19T06:21:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '09d4ce7e-d96d-42f5-aac4-68a604efa023' User entered '19 Jan 2021 06:21:06'	System	19 Jan 2021 13:21:11

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-24T20:51:22', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd0af5544-1990-4ca8-a993-aa519a13e460'	System	25 Jan 2021 03:51:36
User entered 'No (N)'	System	25 Jan 2021 03:51:36

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-24T20:51:29', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd0af5544-1990-4ca8-a993-aa519a13e460'	System	25 Jan 2021 03:51:36
User entered 'No (N)'	System	25 Jan 2021 03:51:36

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-24T20:51:32', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd0af5544-1990-4ca8-a993-aa519a13e460' User entered '24 Jan 2021 20:51:32'	System	25 Jan 2021 03:51:36
	System	25 Jan 2021 03:51:36

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-30T06:54:53', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd29587d6-26a0-4487-aea5-7f10a3b1c55e' User entered 'Yes (Y)'	System	30 Jan 2021 13:55:17
	System	30 Jan 2021 13:55:17

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-30T06:54:59', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd29587d6-26a0-4487-aea5-7f10a3b1c55e'	System	30 Jan 2021 13:55:17
User entered 'No (N)'	System	30 Jan 2021 13:55:17

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-30T06:55:04', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd29587d6-26a0-4487-aea5-7f10a3b1c55e' User entered 'No (N)'	System	30 Jan 2021 13:55:17
	System	30 Jan 2021 13:55:17

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-30T06:55:09', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd29587d6-26a0-4487-aea5-7f10a3b1c55e' User entered 'No (N)'	System	30 Jan 2021 13:55:17
	System	30 Jan 2021 13:55:17

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-01-30T06:55:13', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd29587d6-26a0-4487-aea5-7f10a3b1c55e' User entered '30 Jan 2021 06:55:13'	System	30 Jan 2021 13:55:17
	System	30 Jan 2021 13:55:17

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-07T16:34:03', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '67598dbb-03e2-4dca-9db0-65eb6c1d94c5'	System	07 Feb 2021 23:34:17
User entered 'No (N)'	System	07 Feb 2021 23:34:17

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-07T16:34:08', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '67598dbb-03e2-4dca-9db0-65eb6c1d94c5'	System	07 Feb 2021 23:34:17
User entered 'No (N)'	System	07 Feb 2021 23:34:17

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-07T16:34:10', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '67598dbb-03e2-4dca-9db0-65eb6c1d94c5'	System	07 Feb 2021 23:34:17
User entered '07 Feb 2021 16:34:10'	System	07 Feb 2021 23:34:17

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-15T17:02:28', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '76a2b8e2-7eff-4ea6-987e-af06ad69c067'	System	16 Feb 2021 00:07:23
User entered 'No (N)'	System	16 Feb 2021 00:07:23

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-15T17:02:32', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '76a2b8e2-7eff-4ea6-987e-af06ad69c067'	System	16 Feb 2021 00:07:23
User entered 'No (N)'	System	16 Feb 2021 00:07:23

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-15T17:02:35', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '76a2b8e2-7eff-4ea6-987e-af06ad69c067' User entered '15 Feb 2021 17:02:35'	System	16 Feb 2021 00:07:23
	System	16 Feb 2021 00:07:23

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-22T07:33:44', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '49446731-95bf-4f21-ac3f-0197da75eb1e' User entered 'Yes (Y)'	System	22 Feb 2021 14:34:21
	System	22 Feb 2021 14:34:21

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-22T07:33:48', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '49446731-95bf-4f21-ac3f-0197da75eb1e' User entered 'No (N)'	System	22 Feb 2021 14:34:21

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-22T07:33:51', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '49446731-95bf-4f21-ac3f-0197da75eb1e' User entered 'No (N)'	System	22 Feb 2021 14:34:21

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-22T07:33:58', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '49446731-95bf-4f21-ac3f-0197da75eb1e' User entered 'Yes (Y)'	System	22 Feb 2021 14:34:21
	System	22 Feb 2021 14:34:21

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Please 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-22T07:34:06', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '49446731-95bf-4f21-ac3f-0197da75eb1e'	System	22 Feb 2021 14:34:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Feb 2021 14:34:21

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-02-22T07:34:11', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '49446731-95bf-4f21-ac3f-0197da75eb1e' User entered '22 Feb 2021 07:34:11'	System	22 Feb 2021 14:34:21
	System	22 Feb 2021 14:34:21

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-01T09:44:53-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3867b76e-a101-4f3b-a031-53cb934dc80b' User entered 'No (N)'	System	01 Mar 2021 16:45:07
	System	01 Mar 2021 16:45:07

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-01T09:44:56-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3867b76e-a101-4f3b-a031-53cb934dc80b'	System	01 Mar 2021 16:45:07
User entered 'No (N)'	System	01 Mar 2021 16:45:07

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-01T09:44:59-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '3867b76e-a101-4f3b-a031-53cb934dc80b' User entered '01 Mar 2021 09:44:59'	System	01 Mar 2021 16:45:07
	System	01 Mar 2021 16:45:07

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-06T06:37:04-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '7885fc0b-8063-48d0-b5ac-6eddda3fda56'	System	06 Mar 2021 13:37:14
User entered 'No (N)'	System	06 Mar 2021 13:37:14

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-06T06:37:08-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '7885fc0b-8063-48d0-b5ac-6eddda3fda56'	System	06 Mar 2021 13:37:14
User entered 'No (N)'	System	06 Mar 2021 13:37:14

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-06T06:37:10-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '7885fc0b-8063-48d0-b5ac-6eddda3fda56'	System	06 Mar 2021 13:37:14
User entered '06 Mar 2021 06:37:10'	System	06 Mar 2021 13:37:14

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-13T06:56:49-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd009145c-1d88-43d6-944a-c7831d8d6734'	System	13 Mar 2021 13:56:58
User entered 'No (N)'	System	13 Mar 2021 13:56:58

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-13T06:56:53-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd009145c-1d88-43d6-944a-c7831d8d6734'	System	13 Mar 2021 13:56:58
User entered 'No (N)'	System	13 Mar 2021 13:56:58

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-13T06:56:56-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'd009145c-1d88-43d6-944a-c7831d8d6734'	System	13 Mar 2021 13:56:58
User entered '13 Mar 2021 06:56:56'	System	13 Mar 2021 13:56:58

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-20T06:24:39-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c09fe0e6-b795-467a-849d-2bafb2ea67ec'	System	20 Mar 2021 12:24:49
User entered 'No (N)'	System	20 Mar 2021 12:24:49

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-20T06:24:42-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c09fe0e6-b795-467a-849d-2bafb2ea67ec'	System	20 Mar 2021 12:24:49
User entered 'No (N)'	System	20 Mar 2021 12:24:49

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-20T06:24:44-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'c09fe0e6-b795-467a-849d-2bafb2ea67ec'	System	20 Mar 2021 12:24:49
User entered '20 Mar 2021 06:24:44'	System	20 Mar 2021 12:24:49

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-28T09:32:11-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '38fc1688-96ab-46e5-9ea6-90c6cc1045ca'	System	28 Mar 2021 15:32:20
User entered 'No (N)'	System	28 Mar 2021 15:32:20

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-28T09:32:15-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '38fc1688-96ab-46e5-9ea6-90c6cc1045ca'	System	28 Mar 2021 15:32:20
User entered 'No (N)'	System	28 Mar 2021 15:32:20

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-28T09:32:18-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '38fc1688-96ab-46e5-9ea6-90c6cc1045ca' User entered '28 Mar 2021 09:32:18'	System	28 Mar 2021 15:32:20
	System	28 Mar 2021 15:32:20

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-03T14:54:59-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2c30ba74-e537-4ffc-889f-aaafa2988817'	System	03 Apr 2021 20:55:08
User entered 'No (N)'	System	03 Apr 2021 20:55:08

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-03T14:55:01-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2c30ba74-e537-4ffc-889f-aaafa2988817'	System	03 Apr 2021 20:55:08
User entered 'No (N)'	System	03 Apr 2021 20:55:08

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-03T14:55:05-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '2c30ba74-e537-4ffc-889f-aaafa2988817'	System	03 Apr 2021 20:55:08
User entered '03 Apr 2021 14:55:05'	System	03 Apr 2021 20:55:08

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-11T11:37:20-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '809a555d-fd2d-4001-8c77-b067e7df12e3'	System	11 Apr 2021 17:37:27
User entered 'No (N)'	System	11 Apr 2021 17:37:27

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-11T11:37:22-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '809a555d-fd2d-4001-8c77-b067e7df12e3'	System	11 Apr 2021 17:37:27
User entered 'No (N)'	System	11 Apr 2021 17:37:27

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-11T11:37:25-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '809a555d-fd2d-4001-8c77-b067e7df12e3'	System	11 Apr 2021 17:37:27
User entered '11 Apr 2021 11:37:25'	System	11 Apr 2021 17:37:27

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:14-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered 'Yes (Y)'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:18-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered 'No (N)'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:30-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered 'Yes (Y)'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '0'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '1'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '1'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078' User entered '0'	System	17 Apr 2021 11:41:18
	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078' User entered '0'	System	17 Apr 2021 11:41:18
	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '1'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '1'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '1'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '1'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078' User entered '0'	System	17 Apr 2021 11:41:18
	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '0'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '1'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078' User entered '0'	System	17 Apr 2021 11:41:18
	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078' User entered '0'	System	17 Apr 2021 11:41:18
	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '1'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '0'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:48-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered '0'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Please 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:53-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:40:59-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered 'Yes (Y)'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Please 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:41:03-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078'	System	17 Apr 2021 11:41:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-17T05:41:07-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '5e3c0510-03e8-4516-9f8a-7bfed64a0078' User entered '17 Apr 2021 05:41:07'	System	17 Apr 2021 11:41:18
	System	17 Apr 2021 11:41:18

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-26T07:07:36-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'b0861524-8102-4eef-9f5f-c1326dd58028'	System	26 Apr 2021 13:07:44
User entered 'No (N)'	System	26 Apr 2021 13:07:44

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-26T07:07:38-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'b0861524-8102-4eef-9f5f-c1326dd58028'	System	26 Apr 2021 13:07:44
User entered 'No (N)'	System	26 Apr 2021 13:07:44

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-04-26T07:07:42-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: 'b0861524-8102-4eef-9f5f-c1326dd58028'	System	26 Apr 2021 13:07:44
User entered '26 Apr 2021 07:07:42'	System	26 Apr 2021 13:07:44

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-05-03T22:52:53-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '86364191-c139-48c9-8a6b-f97a3abf71b6'	System	04 May 2021 04:52:59
User entered 'No (N)'	System	04 May 2021 04:52:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

Have you been exposed to someone with 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 (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-05-03T22:52:55-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '86364191-c139-48c9-8a6b-f97a3abf71b6'	System	04 May 2021 04:52:59
User entered 'No (N)'	System	04 May 2021 04:52:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-05-03T22:52:57-06:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '86364191-c139-48c9-8a6b-f97a3abf71b6'	System	04 May 2021 04:52:59
User entered '03 May 2021 22:52:57'	System	04 May 2021 04:52:59

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:15:37

US3332089

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:21:48

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:15:37
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:15:37

US3332089

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:21:48

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 07:24:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-01T09:45:05-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '857f0737-8860-4ef2-b04d-b95e2d15153b'	System	01 Mar 2021 16:45:11
User entered 'No (N)'	System	01 Mar 2021 16:45:11

US3332089

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:21:48

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:24:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AED6F84D-E89C-4E7F-9DBA-1AB114840806)', Time: '2021-03-01T09:45:09-07:00', User OID: 'PatientReportedOutcome (US3332089)', ODM File OID: '857f0737-8860-4ef2-b04d-b95e2d15153b' User entered '01 Mar 2021 09:45:09'	System	01 Mar 2021 16:45:11
	System	01 Mar 2021 16:45:11

US3332089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	14 Jan 2021 16:19:17

US3332089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '9 Nov 2020'	Ashley Bragg (b) (4)	14 Jan 2021 16:19:17

US3332089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:19:17

US3332089

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:19:17

US3332089

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	14 Jan 2021 16:19:22

US3332089

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:07:38
User entered 'I'	System	14 Jan 2021 16:19:22

US3332089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:29
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	14 Jan 2021 16:19:43

US3332089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:29
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '14 Dec 2020'	Ashley Bragg (b) (4)	14 Jan 2021 16:19:43

US3332089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:29
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:19:43

US3332089

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:29
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:19:43

US3332089

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	14 Jan 2021 16:19:50

US3332089

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
User entered 'I'	System	14 Jan 2021 16:19:50

US3332089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:45
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:20:07

US3332089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:45
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '13 Jan 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:20:07

US3332089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:45
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:20:07

US3332089

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:45
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:20:07

US3332089

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:32:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	14 Jan 2021 16:20:12

US3332089

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
User entered 'I'	System	14 Jan 2021 16:20:12

US3332089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:33:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	11 Feb 2021 19:17:44

US3332089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:33:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Feb 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	11 Feb 2021 19:17:44

US3332089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:33:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	11 Feb 2021 19:17:44

US3332089

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:33:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	11 Feb 2021 19:17:44

US3332089

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:33:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	11 Feb 2021 19:17:48

US3332089

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:51:39
User entered '1'	System	11 Feb 2021 19:17:48

US3332089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:26:27

US3332089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered '2 Mar 2021'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:26:27

US3332089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[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 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'Clinic (Clinic)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:26:27

US3332089

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
User entered 'VISIT4'	System	04 Mar 2021 19:26:27

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
User entered empty.	System	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
User entered empty.	System	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
User entered empty.	System	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
User entered empty.	System	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
User entered empty.	System	30 Mar 2021 17:42:55

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50

US3332089

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50

US3332089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:26:49

US3332089

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:43
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered '2 Mar 2021'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:26:49

US3332089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:28:23

US3332089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered '2 Mar 2021'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:28:23

US3332089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:50
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered '09:58'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:28:23

US3332089

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
User entered '2 Mar 2021 09:58'	System	04 Mar 2021 19:28:23

US3332089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:41:55
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	04 Mar 2021 19:28:30

US3332089

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:50
User entered 'I'	System	04 Mar 2021 19:28:30

US3332089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	12 Apr 2021 21:15:57
	(b) (4)	

US3332089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
	(b) (4)	
User entered '12 Apr 2021'	Ashley Bragg (b) (4)	12 Apr 2021 21:15:57
	(b) (4)	

US3332089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	12 Apr 2021 21:15:57

US3332089

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	12 Apr 2021 21:15:57
	(b) (4)	

US3332089

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	12 Apr 2021 21:15:48
	(b) (4)	

US3332089

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 21:15:48

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:37:44
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '15 Apr 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 20:58:58

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:37:44
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '10:40'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 20:58:58

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 10:40'	System	15 Apr 2021 20:58:58

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:37:44
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Safety Call (Safety Call)'	Ashley Bragg (b) (4)	15 Apr 2021 20:58:58

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:37:44
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	15 Apr 2021 20:58:58

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
	(b) (4)	
User entered 'Day 1 (Day 1)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52
	(b) (4)	

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '13 Apr 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '0'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered missing code ND - Not Done.	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered missing code ND - Not Done.	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:03:52

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
	(b) (4)	
User entered 'Day 2 (Day 2)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36
	(b) (4)	

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '14 Apr 2021'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '0'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered missing code ND - Not Done.	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	15 Apr 2021 21:05:36

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered missing code ND - Not Done.	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:05:36

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Severe (Severe)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:05:36

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
	(b) (4)	
User entered 'Day 3 (Day 3)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09
	(b) (4)	

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '15 Apr 2021'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '0'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered missing code ND - Not Done.	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:07:09

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	15 Apr 2021 21:07:09

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '98.3' F	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Severe (Severe)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

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Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'None (None)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:40:00
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:09

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered '15 Apr 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:07:45

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:45

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User closed query 'Per CDM: Please keep this query open until site get the information and updated in EDC. Thank you' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 03:34:21
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
Query 'Per CDM: Please keep this query open until site get the information and updated in EDC. Thank you' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:01:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 19:01:22
User opened query 'Per CDM: Please keep this query open until site get the information and updated in EDC. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:53:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 05:52:59
Query 'Data is required. Please complete.' answered with 'Pending, awaiting lab results' (Site from System).	Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:07:59
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 21:07:45
User entered empty.	Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:07:45

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Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered '15 Apr 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:07:45

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Ashley Bragg (b) (4)	15 Apr 2021 21:07:45

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:07:45

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Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:07:45

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Lab Corps'	Ashley Bragg (b) (4)	15 Apr 2021 21:07:45

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:27
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:07:45

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 19:01:22

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:45
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered '15 Apr 2021'	(b) (4) Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:04

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:45
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered '10:40'	(b) (4) Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:04

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 10:40'	System	16 Apr 2021 18:38:04

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:45
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Safety Call (Safety Call)'	Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:04

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:41:45
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:04

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered '15 Apr 2021'	(b) (4) Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'No (N)'	Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered '15 Apr 2021'	(b) (4) Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

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Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'LabCorps'	Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:42:01
User signature succeeded.	James Peterson (b) (4)	19 Apr 2021 19:41:41
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4)	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 15 Apr 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 18:38:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:02
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 17:45:58
User entered '25 Sep 2020'	Sean Hansen (b) (4)	28 Sep 2020 23:33:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:02
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 17:46:00
User entered '08:00'	Sean Hansen (b) (4)	28 Sep 2020 23:33:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:02
User entered '25 Sep 2020 08:00'	System	28 Sep 2020 23:33:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:02
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 17:46:11
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Sean Hansen (b) (4)	28 Sep 2020 23:33:06
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:21:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:02
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:46:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	28 Sep 2020 23:33:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 8 (Day 8)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:10:19
User entered 'Day 1 (Day 1)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:43:37

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per CDM: please, confirm what has been updated as the response does not show any update has ben made or confirm the date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:24:48
Query 'Per CDM: please, confirm what has been updated as the response does not show any update has ben made or confirm the date.' answered with 'all data on this ecrf page for day 8 is correct as entered.' (Site from DM).	Colby Bostock (b) (4) (b) (4)	17 Nov 2020 22:02:22
User opened query 'Per CDM: please, confirm what has been updated as the response does not show any update has ben made or confirm the date.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 13:55:53
User closed query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (25SEP2020) or update accordingly' (Site from DM).		13 Nov 2020 13:55:53
Query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (25SEP2020) or update accordingly' answered with 'UPDATED' (Site from DM).		10 Nov 2020 23:10:26
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact Date are the same (25SEP2020) or update accordingly' (Site from DM).		09 Nov 2020 03:33:16
DataPoint Verified.		30 Oct 2020 17:46:34
User closed query 'Per ETRTR: Please add Symptoms data from dates previous to Illness Visit and after Illness Visit, thanks.' (Site from CRA).		29 Oct 2020 21:27:45
Query 'Per ETRTR: Please add Symptoms data from dates previous to Illness Visit and after Illness Visit, thanks.' answered with 'Logs updated.' (Site from CRA).	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:58:12
User opened query 'Per ETRTR: Please add Symptoms data from dates previous to Illness Visit and after Illness Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 21:00:31
User entered '25 Sep 2020'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:43:37

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:47:06
User entered '98'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 17:47:08
User entered '98.9' F	Sean Hansen (b) (4)	28 Sep 2020 23:43:37
	(b) (4)	

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:47:11
User entered 'None (None)'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
DataPoint Un-verified.	Sean Hansen (b) (4)	30 Oct 2020 18:07:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sean Hansen (b) (4)	30 Oct 2020 18:07:38
DataPoint Verified.	(b) (4)	30 Oct 2020 17:47:14
User entered 'None (None)'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
DataPoint Un-verified.	Sean Hansen (b) (4)	30 Oct 2020 18:07:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sean Hansen (b) (4)	30 Oct 2020 18:07:38
DataPoint Verified.	(b) (4)	30 Oct 2020 17:47:15
User entered 'None (None)'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 17:47:18
User entered 'None (None)'	(b) (4), (b) (6)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 17:47:23
User entered 'Moderate (Moderate)'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37
	(b) (4)	

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:47:35
User entered 'Moderate (Moderate)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:47:55
User entered 'Moderate (Moderate)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 17:47:58
User entered 'None (None)'	(b) (4), (b) (6)	28 Sep 2020 23:43:37
	Sean Hansen (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:00
User entered 'None (None)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:43:37

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:01
User entered 'None (None)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:03
User entered 'None (None)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 17:48:04
User entered 'None (None)'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:07
User entered 'Moderate (Moderate)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:43:37

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 17:48:09
User entered 'Moderate (Moderate)'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37
	(b) (4)	

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 17:48:14
User entered 'None (None)'	Sean Hansen (b) (4)	28 Sep 2020 23:43:37
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:47:48
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 18:07:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sean Hansen (b) (4)	30 Oct 2020 18:07:38
DataPoint Verified.	(b) (4)	30 Oct 2020 17:48:16
User entered 'None (None)'	(b) (4), (b) (6)	28 Sep 2020 23:43:37
	Sean Hansen (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:10:43
User entered 'Day 2 (Day 2)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:41
User entered '26 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:44
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:46
User entered '98.6' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:48:54
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:25
User closed query 'per source, this is severe. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:46:33
Query 'per source, this is severe. please verify.' answered with 'updated per query' (Site from CRA).	Sean Hansen (b) (4)	30 Oct 2020 18:12:26
User entered 'Severe (Severe)' reason for change:	(b) (4)	
Data Entry Error	Sean Hansen (b) (4)	30 Oct 2020 18:09:44
User opened query 'per source, this is severe. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 17:54:00
DataPoint Un-verified.		30 Oct 2020 17:50:21
DataPoint Verified.		30 Oct 2020 17:48:59
User entered 'Moderate (Moderate)'	Ty Henry (b) (4)	09 Oct 2020 20:32:27
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:49:01
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:25
User closed query 'per source, this is None. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:46:39
Query 'per source, this is None. please verify.'	Sean Hansen (b) (4)	30 Oct 2020 18:12:31
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Sean Hansen (b) (4)	30 Oct 2020 18:09:44
User opened query 'per source, this is None. please verify.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:54:45
DataPoint Un-verified.		30 Oct 2020 17:54:21
DataPoint Verified.		30 Oct 2020 17:49:07
User entered 'Moderate (Moderate)'	Ty Henry (b) (4)	09 Oct 2020 20:32:27
	(b) (4)	

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Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:54:57
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:54:59
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:01
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:02
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:55:04
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User closed query 'per source, this is None. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:46:43
Query 'per source, this is None. please verify.'	Sean Hansen (b) (4)	30 Oct 2020 18:12:35
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Sean Hansen (b) (4)	30 Oct 2020 18:09:44
	(b) (4)	
User opened query 'per source, this is None. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 17:57:44
User entered 'Moderate (Moderate)'	Ty Henry (b) (4)	09 Oct 2020 20:32:27
	(b) (4)	

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Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User closed query 'per source, this is None. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:46:46
Query 'per source, this is None. please verify.'	Sean Hansen (b) (4)	30 Oct 2020 18:12:39
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Sean Hansen (b) (4)	30 Oct 2020 18:09:44
User opened query 'per source, this is None. please verify.' (Site from CRA).	(b) (4)	30 Oct 2020 17:58:07
User entered 'Moderate (Moderate)'	Ty Henry (b) (4)	09 Oct 2020 20:32:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:58:20
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:58:22
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:32:27

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:10:57
User entered 'Day 3 (Day 3)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:58:48
User entered '27 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:58:49
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:58:51
User entered '98.0' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:47
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:59:51
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User closed query 'per source, this is Moderate. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:46:16
Query 'per source, this is Moderate. please verify.' answered with 'updated per query' (Site from CRA).	Sean Hansen (b) (4)	30 Oct 2020 18:11:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	30 Oct 2020 18:11:03
User opened query 'per source, this is Moderate. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:04:31
User entered 'Severe (Severe)'	Ty Henry (b) (4)	09 Oct 2020 20:33:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User closed query 'per source, this is None. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:46:23
Query 'per source, this is None. please verify.'	Sean Hansen (b) (4)	30 Oct 2020 18:11:27
answered with 'updated per query' (Site from CRA).	(b) (4)	
User entered 'None (None)' reason for change: Data Entry Error	Sean Hansen (b) (4)	30 Oct 2020 18:11:03
User opened query 'per source, this is None. please verify.' (Site from CRA).	(b) (4)	
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	30 Oct 2020 18:05:44
	Ty Henry (b) (4)	09 Oct 2020 20:33:59
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:04
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:05
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:07
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:08
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:11
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:12
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:14
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:17
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:19
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:20
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:33:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:11:10
User entered 'Day 4 (Day 4)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:51
User entered '28 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:55
User entered '99'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:36:57

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:06:57
User entered '97.1' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User closed query 'per source, this is Moderate. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:46:00
Query 'per source, this is Moderate. please verify.' answered with 'Updated per query' (Site from CRA).	Sean Hansen (b) (4)	30 Oct 2020 18:14:42
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Sean Hansen (b) (4)	30 Oct 2020 18:14:29
User opened query 'per source, this is Moderate. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:07:52
User entered 'None (None)'	Ty Henry (b) (4)	09 Oct 2020 20:36:57
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User closed query 'per source, this is Moderate. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:46:03
Query 'per source, this is Moderate. please verify.' answered with 'Updated per query' (Site from CRA).	Sean Hansen (b) (4)	30 Oct 2020 18:14:47
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	30 Oct 2020 18:14:29
User opened query 'per source, this is Moderate. please verify.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 18:08:20
User entered 'None (None)'	Ty Henry (b) (4)	09 Oct 2020 20:36:57

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:08:36
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:08:38
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:08:49
User entered 'Severe (Severe)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:08:50
User entered 'Severe (Severe)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:09:15
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:09:18
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:09:21
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:09:29
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:09:57
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:10:07
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:10:08
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:10:11
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:10:14
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:10:19
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:36:57

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:11:34
User entered 'Day 5 (Day 5)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:10:40
User entered '29 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4)	09 Oct 2020 20:38:50

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:10:42
User entered '99'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:11:09
User entered '97.0' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:11:11
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:11:13
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:11:15
User entered 'None (None)'	Ty Henry (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:11:17
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:11:26
User entered 'Severe (Severe)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:11:28
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:02
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:04
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:05
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:17
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:41
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:47
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:12:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:38:50

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:11:48
User entered 'Day 6 (Day 6)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:13:40
User entered '30 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:13:42
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:13:44
User entered '97.4' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:13:58
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:00
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:03
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:05
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:20
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:21
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:39
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:51
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:14:53
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:42:53

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:12:02
User entered 'Day 7 (Day 7)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:24
User entered '01 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:26
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:29
User entered '97.0' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:54
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:56
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:15:58
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:08
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:10
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:12
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:23
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Oct 2020 20:49:06
User entered 'None (None)'	(b) (4)	
	Ty Henry (b) (4)	09 Oct 2020 20:44:25
	(b) (4)	

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:36
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:38
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:16:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Oct 2020 20:49:06
User entered 'None (None)'	(b) (4) Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'please verify.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:35:23
DataPoint Verified.		04 Nov 2020 16:35:21
Query 'please verify.' answered with 'confirmed correct as entered ' (Site from CRA).		30 Oct 2020 23:42:12
User opened query 'please verify.' (Site from CRA).		30 Oct 2020 18:19:59
DataPoint Un-verified.		30 Oct 2020 18:17:00
DataPoint Verified.		30 Oct 2020 18:16:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:44:25

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:12:16
User entered 'Day 8 (Day 8)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:22
User entered '02 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4)	09 Oct 2020 20:46:42

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:24
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:34
User entered '98.0' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:51
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:20:59
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:21:00
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:21:02
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:21:11
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:21:12
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:04
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:22:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 07:01:25
User closed query 'both Mild and None ticked in source, please clarify. ' (Site from CRA).		02 Nov 2020 16:36:29
Query 'both Mild and None ticked in source, please clarify. ' answered with 'confirmed and corrected source data ' (Site from CRA).		30 Oct 2020 23:43:41
User entered 'None (None)' reason for change: Data Entry Error		30 Oct 2020 23:43:36
User opened query 'both Mild and None ticked in source, please clarify. ' (Site from CRA).		30 Oct 2020 18:29:18
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:25:18
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:46:42

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:12:31
User entered 'Day 9 (Day 9)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:33
User entered '03 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:38
User entered '97'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:51:18

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:39
User entered '97.1' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:42
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:29:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:30:12
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:30:13
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:30:15
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:30:23
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:30:25
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:30:51
User entered 'Severe (Severe)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:02
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:04
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:14
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:15
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:16
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:19
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:21
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:22
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:51:18

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:12:46
User entered 'Day 10 (Day 10)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:36
User entered '04 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:39
User entered '97'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:41
User entered '97.3' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:51
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:31:58
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:07
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:09
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:21
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:35
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:38
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:42
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:32:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:52:52

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:09
User entered 'Day 11 (Day 11)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:10
User entered '05 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:15
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:18
User entered '98.2' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:54
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:57
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:33:58
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:34:32
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:34:34
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:02
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:04
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:06
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:07
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:10
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:11
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:14
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:15
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:54:40

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:20
User entered 'Day 12 (Day 12)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:42
User entered '06 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:44
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:45
User entered '98.2' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:47
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:35:55
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:10
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:12
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:14
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:36:28
User entered 'None (None)'	Ty Henry (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:36:30
User entered 'None (None)'	Ty Henry (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:32
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:33
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:34
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:36
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:55:35

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:34
User entered 'Day 13 (Day 13)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:36:52
User entered '07 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:37:39
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:37:49
User entered '97.0' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:37:51
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:37:53
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:01
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:03
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:06
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:08
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:10
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:12
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:36
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:38
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:39
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:42
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:05

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 21 (Day 21)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:13:49
User entered 'Day 14 (Day 14)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:38:58
User entered '08 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	Ty Henry (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:00
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:04
User entered '97.1' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:12
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:13
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:39:15
User entered 'None (None)'	Ty Henry (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:17
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:18
User entered 'Moderate (Moderate)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:35
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:41
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:39:43
User entered 'None (None)'	Ty Henry (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:47
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:53
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:39:55
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:57:51

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 22 (Day 22)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:14:12
User entered 'Day 15 (Day 15)'	(b) (4), (b) (6)	20 Oct 2020 18:44:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:40:30
User entered '9 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:40:35
User entered 'l'	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered empty.	System	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 18:44:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 23 (Day 23)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:14:32
User entered 'Day 16 (Day 16)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:40:57
User entered '10 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:13
User entered '97'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:41:15
User entered '97.2' F	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:16
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:18
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:21
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:22
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:24
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:26
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:27
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:32
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:41:35
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:41:37
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:38
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:40
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:42
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:44
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:41:45
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:44:59

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per CDM: Please review line 18 of the Symptom Log and inactivate this line if not needed.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 08:32:07
Query 'Per CDM: Please review line 18 of the Symptom Log and inactivate this line if not needed.' answered with 'correct as entered' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:42:26
User opened query 'Per CDM: Please review line 18 of the Symptom Log and inactivate this line if not needed.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:45:37
User entered 'Day 24 (Day 24)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:14:50
User entered 'Day 17 (Day 17)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 26OCT2020. Please reconcile or clarify.' canceled (Site from DM).	(b) (4) (u) (4), (b) (6)	10 Nov 2020 20:15:33
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 26OCT2020. Please reconcile or clarify.' (Site from DM).		09 Nov 2020 03:32:06
User closed query 'Per source, this happened on 12 Oct 20. Please verify. ' (Site from CRA).		04 Nov 2020 16:36:25
DataPoint Verified.		04 Nov 2020 16:36:23
Query 'Per source, this happened on 12 Oct 20. Please verify. ' answered with 'assessment was 10/11 crc signed 10.12' (Site from CRA).		30 Oct 2020 23:45:32
User entered '11 Oct 2020' reason for change: Data Entry Error		30 Oct 2020 23:45:26
User opened query 'Per source, this happened on 12 Oct 20. Please verify. ' (Site from CRA).		30 Oct 2020 18:43:45
User entered '17 Oct 2020'		20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:01:25
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:06
User entered '99'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:08
User entered '97.6' F	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:10
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:12
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:14
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:15
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:17
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:18
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:21
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:23
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:24
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:26
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:29
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:44:31
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:44:33
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:44:35
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:37
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:44:38
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 18:45:31

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per CDM: Please consider recording Not Done instead of NA for Symptom Log lines 19 through Lines 25.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 12:15:24
Query 'Per CDM: Please consider recording Not Done instead of NA for Symptom Log lines 19 through Lines 25.' answered with 'updated' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:41:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:41:09
User opened query 'Per CDM: Please consider recording Not Done instead of NA for Symptom Log lines 19 through Lines 25.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:47:57
User entered 'NA' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:38:43

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	14 Jan 2021 23:41:09
User entered empty.	System	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:38:43

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '19 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 23:41:09
User entered 'NA' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:43:12

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	14 Jan 2021 23:41:09
User entered empty.	System	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:43:12

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '20 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 23:44:49
User entered 'NA' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	14 Jan 2021 23:44:49
User entered empty.	System	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:44:42

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 23:44:49
User entered 'NA' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:46:46

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	14 Jan 2021 23:44:49
User entered empty.	System	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:46:46

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 23:44:49
User entered 'NA' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:48:06

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	14 Jan 2021 23:44:49
User entered empty.	System	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:48:06

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 23:44:49
User entered 'NA' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	14 Jan 2021 23:44:49
User entered empty.	System	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:49:44

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 23:44:49
User entered 'NA' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
User entered '%'	System	14 Jan 2021 23:44:49
User entered empty.	System	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Not Done (Not Done)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:21:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:19
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:43:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:51:08

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:48:40
User entered '25 Sep 2020'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:44:34

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:49:40
User entered 'Yes (Y)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:44:34

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:37:03
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)	02 Oct 2020 07:32:12
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated per query' (Site from System).	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:46:40
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	28 Sep 2020 23:44:34
User entered 'Yes (Y)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:44:34

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 18:51:15
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:15:09
User entered '24 Sep 2020'	Sean Hansen (b) (4)	28 Sep 2020 23:44:34

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:51:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:44:34

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:42
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:44:34

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Folder: Covid-19 Assessment 25 Sep 2020

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)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:51:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:15:09
User entered 'Yes (Y)'	Sean Hansen (b) (4)	28 Sep 2020 23:44:34

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:21:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:15:09
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 23:45:33
User entered 'Mid Town Manor Sophia Rapid PCR' reason for change: Data Entry Error	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:45:33
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 23:44:34
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:44:34

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Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:01:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 19:15:09
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 23:45:33
User entered 'No (N)' reason for change: Data Entry Error	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:45:33
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 23:44:34
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:44:34

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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)	01 May 2021 17:57:27
User entered 'I'	System	28 Sep 2020 23:44:34

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:53:57
User entered 'No (N)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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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)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:53:59
User entered 'No (N)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 18:54:13
User entered 'No (N)'	Sean Hansen (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 07:32:39
Query 'Data is required. Please complete.' answered with 'Not Done' (Site from System).	Sean Hansen (b) (4)	28 Sep 2020 23:49:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 23:49:09
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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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)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:54:45
User entered 'No (N)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Form: Covid-19 Severity Assessment

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:55:36
User entered 'No (N)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

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Generated On: 11 Aug 2021 22:21:48

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

US3332089

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:41:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query ' Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 12:16:00
Query ' Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.' answered with 'updated' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:39:56
DataPoint Un-verified.	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:39:49
User entered 'No (N)' reason for change: Data Entry Error	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:39:49
User opened query ' Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 15:49:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:41:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Un-verified.	(b) (4)	
	Colby Bostock (b) (4)	14 Jan 2021 23:39:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 23:39:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:41:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Un-verified.	(b) (4)	
	Colby Bostock (b) (4)	14 Jan 2021 23:39:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 23:39:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:41:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Un-verified.	(b) (4)	
	Colby Bostock (b) (4)	14 Jan 2021 23:39:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 23:39:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:41:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Un-verified.	(b) (4)	
	Colby Bostock (b) (4)	14 Jan 2021 23:39:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 23:39:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:41:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Un-verified.	(b) (4)	
	Colby Bostock (b) (4)	14 Jan 2021 23:39:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 23:39:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:41:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Un-verified.	(b) (4)	
	Colby Bostock (b) (4)	14 Jan 2021 23:39:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 23:39:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:49:09
	(b) (4)	

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Folder: Covid-19 Assessment 25 Sep 2020

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Generated On: 11 Aug 2021 22:21:48

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:55:58
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 23:51:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 23:51:27
User entered 'No (N)' reason for change: Data Entry Error	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:51:27
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 23:49:09
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

US3332089

Folder: Covid-19 Assessment 25 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:21:48

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:02:22
User entered empty.	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:49:09

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Folder: Covid-19 Assessment 25 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:21:48

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:57:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:02:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 22:36:31

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 12:52:27
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'The tracking number is unknown for this shipment.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 22:02:09
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:54:28
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 08:54:28
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'accession # 1f606627498' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:43:44
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 08:19:18

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 06:28:52
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	28 Dec 2020 21:25:53
' answered with 'the sample was shipped and we got confirmation of receipt 1F60JO0' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28SEP2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	04 Dec 2020 10:24:23
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.28SEP2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	04 Dec 2020 10:01:42
' canceled (Site from DM).		

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.28SEP2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 09:52:58
User accepted default value 'Day 3 (Day 3)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:21:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:00:15
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:04:41
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3 with date of 29SEP2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:21:53
Query 'Per GCL Lab Recon: GCL has Saliva Day 3 with date of 29SEP2020. Please reconcile or clarify' answered with 'saliva was collected 9/28/20 date entered in preclrus is incorrect' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 21:32:31
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3 with date of 29SEP2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 11:10:30
User entered '28 Sep 2020'	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:21:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:03:02
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	0 Nov 2020 07:04:41
User closed query 'per source, this happened on 29 Sep20. please verify.' (Site from CRA).		2 Nov 2020 16:37:36
Query 'per source, this happened on 29 Sep20. please verify.' answered with 'updated' (Site from CRA).		0 Oct 2020 23:46:38
User entered '29 Sep 2020' reason for change: Data Entry Error		0 Oct 2020 23:46:33
User opened query 'per source, this happened on 29 Sep20. please verify.' (Site from CRA).		0 Oct 2020 19:03:35
User entered '30 Sep 2020'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:21:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:03:47
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:03:49
User entered '01 Oct 2020'	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:21:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:03:56
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:03:57
User entered '02 Oct 2020'	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:21:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:04:11
User entered 'Yes (Y)'	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded for Day 14 in EDC, however the same is reported under Day 14 with date 09OCT2020 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) (4), (b) (6)	13 Nov 2020 06:56:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:04:41
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded for Day 14 in EDC, however the same is reported under Day 14 with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'day 14 sample was collected 10/7/20 entered incorrectly in preclarus cannot update data entered correctly ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:22:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07OCT2020 is recorded for Day 14 in EDC, however the same is reported under Day 14 with date 09OCT2020 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)	29 Oct 2020 10:05:43
User entered '07 Oct 2020'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:21:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'This not have done per source. please Clarify.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:31:19
		04 Nov 2020 16:31:12
Query 'This not have done per source. please Clarify.' answered with 'updated source ' (Site from CRA).		30 Oct 2020 23:49:32
User opened query 'This not have done per source. please Clarify.' (Site from CRA).		30 Oct 2020 19:06:26
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:31:23
User entered '15 Oct 2020'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:21:48

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Ty Henry (b) (4) (b) (4)	16 Oct 2020 15:01:01

US3332089

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:21:48

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:36:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per CDM Requery-Response noted,however,'was saliva acaollected?' is expected to be 'Yes' since Date of collection is provided.Kindly consider to update response for the field 'Was Saliva Collected appropriately .Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 06:01:13
Query 'Per CDM Requery-Response noted,however,'was saliva acaollected?' is expected to be 'Yes' since Date of collection is provided.Kindly consider to update response for the field 'Was Saliva Collected appropriately .Thank you.' answered with 'updated' (Site from DM).	Colby Bostock (b) (4) (b) (4)	18 Jan 2021 17:52:26
DataPoint Un-verified.	Colby Bostock (b) (4) (b) (4)	18 Jan 2021 17:52:19
User entered 'Yes (Y)' reason for change: Per Query Resolution	Colby Bostock (b) (4) (b) (4)	18 Jan 2021 17:52:19
User opened query 'Per CDM Requery-Response noted,however,'was saliva acaollected?' is expected to be 'Yes' since Date of collection is provided.Kindly consider to update response for the field 'Was Saliva Collected appropriately .Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 11:54:12
User closed query 'Per CDM: Date of collection recorded as 26OCT2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as No. Please review and update the response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 11:54:12
Query 'Per CDM: Date of collection recorded as 26OCT2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as No. Please review and update the response as appropriate. ' answered with 'accession # 1f619238626' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:44:22
User opened query 'Per CDM: Date of collection recorded as 26OCT2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as No. Please review and update the response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:47:46

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EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:21:48

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:04:41
DataPoint Un-verified.		05 Nov 2020 19:50:30
User entered 'No (N)' reason for change: Per Query Resolution		05 Nov 2020 19:50:30
DataPoint Verified.		30 Oct 2020 19:07:25
User entered 'Yes (Y)' reason for change: Data Entry Error		26 Oct 2020 21:28:54
User entered 'No (N)' reason for change: Data Entry Error	Ty Henry (b) (4)	16 Oct 2020 15:01:50
User entered 'Yes (Y)'	(b) (4)	
	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:36:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26 Oct 2020 was previously updated and removed, please consider to review and confirm if it should have been removed. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 06:26:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26 Oct 2020 was previously updated and removed, please consider to review and confirm if it should have been removed. Thank you. ' answered with 'RE ADDED' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 21:27:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 21:27:02
User entered '26 Oct 2020' reason for change: Data Entry Error		28 Dec 2020 21:27:02
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26 Oct 2020 was previously updated and removed, please consider to review and confirm if it should have been removed. Thank you. ' (Site from DM).		30 Nov 2020 06:09:19
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Thank you for confirming the correct visit for the Sample. However, per response, if the sample was collected then please record the data on this form,' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:50:29
Query 'Per GCL Lab Reconciliation Requery: Saliva: Thank you for confirming the correct visit for the Sample. However, per response, if the sample was collected then please record the data on this form,' answered with 'no sample not collected' (Site from DM).	Colby Bostock (b) (4) (b) (4)	17 Nov 2020 21:59:57
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Thank you for confirming the correct visit for the Sample. However, per response, if the sample was collected then please record the data on this form,' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:06:12

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 07:06:12
	(b) (4), (b) (6)	10 Nov 2020 07:04:41
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'SALIVA COLLECTED WAS AT ILLNESS CAONVALESCENT VISIT DAY 29 SHOULD IT BE REMOVED HERE?' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 19:50:43
	(b) (4), (b) (6)	05 Nov 2020 19:50:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:50:30
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 09:49:45
	(b) (4), (b) (6)	30 Oct 2020 19:07:27
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:28:54
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	16 Oct 2020 15:01:50
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	16 Oct 2020 15:01:50
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	16 Oct 2020 15:01:01
User entered '26 Oct 2020'	Ty Henry (b) (4)	16 Oct 2020 15:01:01
	(b) (4)	

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EAB) (1725)

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:56:41
User closed query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 21:28:33
Query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' answered with 'Saliva page updated.' (Site from CRA).	Ty Henry (b) (4)	16 Oct 2020 15:02:22
	(b) (4)	
User opened query 'Per ETRTR: Please complete data entry for Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 20:59:10
User entered 'Yes (Y)'	Sean Hansen (b) (4)	28 Sep 2020 23:54:17
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:56:43
User entered '25 Sep 2020'	Sean Hansen (b) (4)	28 Sep 2020 23:54:17
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:56:45
User entered 'Home (Home)'	Sean Hansen (b) (4)	28 Sep 2020 23:54:17
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	28 Sep 2020 23:54:17

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:56:56
User entered 'Yes (Y)'	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:56:58
User entered '25 Sep 2020'	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:02
User entered '19:23'	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 19:23'	System	28 Sep 2020 23:55:39

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:19
User closed query 'Per CDM: Please consider recording this row as ND - Not done. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:11:35
Query 'Per CDM: Please consider recording this row as ND - Not done. Thank you!' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4)	06 Oct 2020 15:36:27
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4)	06 Oct 2020 15:36:18
	(b) (4)	
User opened query 'Per CDM: Please consider recording this row as ND - Not done. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:39:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 07:38:57
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	Sean Hansen (b) (4)	28 Sep 2020 23:55:54
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 23:55:39
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	
DataPoint set to visible.	System	28 Sep 2020 23:54:17

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:21
User closed query 'Per CDM: Please consider recording this row as ND - Not done. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:11:37
Query 'Per CDM: Please consider recording this row as ND - Not done. Thank you!' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4)	06 Oct 2020 15:36:34
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4)	06 Oct 2020 15:36:18
	(b) (4)	
User opened query 'Per CDM: Please consider recording this row as ND - Not done. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 07:39:15
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 07:38:58
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	Sean Hansen (b) (4)	28 Sep 2020 23:55:57
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 23:55:39
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	
DataPoint set to visible.	System	28 Sep 2020 23:54:17

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:29
User entered '98.9' F	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:30
User entered 'Oral (Oral)'	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:03:09
User entered empty.	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:39
User entered '76'	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 23:55:39

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:40
User entered '16'	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 23:55:39

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:51
User entered '121'	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 23:55:39

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:57:52
User entered '93'	Sean Hansen (b) (4)	28 Sep 2020 23:55:39
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 23:55:39

US3332089

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:58:02
User entered 'Yes (Y)'	Sean Hansen (b) (4)	28 Sep 2020 23:56:14
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:58:03
User entered '25 Sep 2020'	Sean Hansen (b) (4)	28 Sep 2020 23:56:14
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:21:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:58:14
User entered 'Yes (Y)'	Sean Hansen (b) (4) (b) (4)	28 Sep 2020 23:56:28

US3332089

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 18:58:16
User entered '25 Sep 2020'	Sean Hansen (b) (4)	28 Sep 2020 23:56:28
	(b) (4)	

US3332089

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:36
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	15 Apr 2021 21:08:25

US3332089

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:36
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '15 Apr 2021'	Ashley Bragg (b) (4)	15 Apr 2021 21:08:25

US3332089

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:33:36
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Clinic (Clinic)'	Ashley Bragg (b) (4)	15 Apr 2021 21:08:25

US3332089

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	15 Apr 2021 21:08:25

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '15 Apr 2021'	Ashley Bragg (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '14:00'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 14:00'	System	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered missing code ND - Not Done.	(b) (4) Ashley Bragg (b) (4)	15 Apr 2021 21:09:18
DataPoint set to visible.	(b) (4) System	15 Apr 2021 21:08:25

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered missing code ND - Not Done.	(b) (4) Ashley Bragg (b) (4)	15 Apr 2021 21:09:18
DataPoint set to visible.	(b) (4) System	15 Apr 2021 21:08:25

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '98.3' F	Ashley Bragg (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Oral (Oral)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '67'	Ashley Bragg (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '18'	Ashley Bragg (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '109'	Ashley Bragg (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:01
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '76'	Ashley Bragg (b) (4)	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 21:09:18

US3332089

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:09
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	15 Apr 2021 21:09:26

US3332089

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:34:09
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '15 Apr 2021'	Ashley Bragg (b) (4)	15 Apr 2021 21:09:26

US3332089

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:21:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:57
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:09:35

US3332089

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:36:57
User signature succeeded.	James Peterson (b) (4)	16 Apr 2021 15:50:35
User entered '15 Apr 2021'	(b) (4) Ashley Bragg (b) (4) (b) (4)	15 Apr 2021 21:09:35

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26OCT2020 is reported under UNSCHEDULED visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for Convalescence visit and update the details in Saliva collection log under Day 28. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 06:11:08
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26OCT2020 is reported under UNSCHEDULED visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for Convalescence visit and update the details in Saliva collection log under Day 28. Else clarify, thank you' answered with 'asked lab to update to day 28 correct as entered here' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:55:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26OCT2020 is reported under UNSCHEDULED visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for Convalescence visit and update the details in Saliva collection log under Day 28. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:25:36
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:12:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 21:26:50

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:12:11
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 21:26:50

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:12:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Oct 2020 21:26:50

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User entered 'SICKD28'	System	26 Oct 2020 21:26:50

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:12:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:12:38
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:12:43
User entered '09:55'	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User entered '26 Oct 2020 09:55'	System	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:12:51
User entered '66.3' in	(b) (4), (b) (6)	26 Oct 2020 21:27:55
DataPoint set to visible.	System	26 Oct 2020 21:26:50

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:12:54
User entered '205.0' lb	(b) (4), (b) (6)	26 Oct 2020 21:27:55
DataPoint set to visible.	System	26 Oct 2020 21:26:50

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:14:52
User entered '98.7' F	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:14:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:03:34
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:15:10
User entered '88'	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User entered 'bpm'	System	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:15:12
User entered '12'	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User entered 'breaths/min'	System	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:15:18
User entered '107'	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User entered 'mmHg'	System	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:15:19
User entered '77'	(b) (4), (b) (6)	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User entered 'mmHg'	System	26 Oct 2020 21:27:55

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:15:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 21:28:01

US3332089

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:15:38
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 21:28:01

US3332089

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:21:48

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:18:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 21:28:08

US3332089

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:21:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 26 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 07:36:53
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 26 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'site used unscheduled kit per sponsor d/t kit shortage ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:29:04
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 26 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:21:21
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:18:48
User entered '26 Oct 2020' reason for change: Data Entry Error		26 Oct 2020 21:28:14
User entered empty.		26 Oct 2020 21:28:08

US3332089

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

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:42:26
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:01:24

US3332089

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

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:42:26
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:01:24

US3332089

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

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:42:26
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Clinic (Clinic)'	Colby Bostock (b) (4)	11 Jan 2021 21:01:24

US3332089

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

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 21:01:24

US3332089

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:43:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:02:36

US3332089

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:13:54

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:43:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 04:40:48
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'subject did not receive dose 2 due to testing positive for covid-19 after 1st dose' (Site from System).	Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:03:45
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	11 Jan 2021 21:02:36
User entered 'Yes (Y)'	Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:02:36

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:13:54

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:43:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:02:36

US3332089

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:43:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:02:36

US3332089

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:43:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	System	20 Jan 2021 09:35:05
User entered 'mRNA-1273 (mRNA-1273)'	Colby Bostock (b) (4)	11 Jan 2021 21:02:36
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:43:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Not Administered (NA)' reason for change: Per Query Resolution	(b) (4)	
	Kenadie Hamblin (b) (4)	08 Feb 2021 21:54:20
User entered empty.	(b) (4)	
	Colby Bostock (b) (4)	11 Jan 2021 21:02:36
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:43:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:02:36

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered empty.	System	11 Jan 2021 21:02:36

US3332089

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

Form: Unblinding

Generated On: 11 Aug 2021 22:21:48

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'I'	System	08 Feb 2021 21:54:20
User entered empty.	System	11 Jan 2021 21:02:36

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered empty.	System	08 Feb 2021 21:59:06
DataPoint set to visible.	System	08 Feb 2021 21:54:20

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered empty.	System	08 Feb 2021 21:59:06
DataPoint set to visible.	System	08 Feb 2021 21:54:20

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User accepted default value 'Pre-Dose (PREDOSE)'	Kenadie Hamblin (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '10:03'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered '11 Jan 2021 10:03'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '98.6' F	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Oral (Oral)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '74'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'bpm'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '18'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'breaths/min'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '124'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'mmHg'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '89'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'mmHg'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered missing code ND - Not Done.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:21:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered empty.	System	08 Feb 2021 21:59:06
DataPoint set to visible.	System	08 Feb 2021 21:54:20

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User accepted default value 'Post-Dose (POSTDOSE)'	Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '10:58'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered '11 Jan 2021 10:58'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '98.2' F	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Oral (Oral)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '63'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'bpm'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '16'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'breaths/min'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '130'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'mmHg'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:46:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '87'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:06

US3332089

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'mmHg'	System	08 Feb 2021 21:59:06

US3332089

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:16

US3332089

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:47:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 21:59:16

US3332089

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:48:17
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	08 Feb 2021 22:00:09

US3332089

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:48:17
User entered '11 Jan 2021'	Kenadie Hamblin (b) (4)	08 Feb 2021 22:00:09

US3332089

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:48:17
User entered 'Urine (URINE)'	Kenadie Hamblin (b) (4)	08 Feb 2021 22:00:09

US3332089

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:48:17
User entered 'Negative (NEGATIVE)'	Kenadie Hamblin (b) (4)	08 Feb 2021 22:00:09

US3332089

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:43:45
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'updated' (Site from DM).	Ashley Bragg (b) (4) (b) (4)	26 Feb 2021 17:00:53
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:48:17
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 13:57:14
User entered 'No (N)'	Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:00:09

US3332089

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:44:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User closed query 'AS FSH wasn't collected, please remove the date of collection.' (Site from CRA).	(b) (4)	
Query 'AS FSH wasn't collected, please remove the date of collection.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 20:14:22
Query 'AS FSH wasn't collected, please remove the date of collection.' answered with 'updated' (Site from CRA).	Ashley Bragg (b) (4)	26 Feb 2021 17:00:59
User entered empty; reason for change Data Entry Error	(b) (4)	
User opened query 'AS FSH wasn't collected, please remove the date of collection.' (Site from CRA).	Ashley Bragg (b) (4)	26 Feb 2021 17:00:36
DataPoint Un-verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:51:09
		25 Feb 2021 19:48:45
		25 Feb 2021 19:48:17
User entered '11 Jan 2021'	Kenadie Hamblin (b) (4)	08 Feb 2021 22:00:09
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:44:21
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User closed query 'AS FSH wasn't collected, please remove the time of collection.' (Site from CRA).	(b) (4)	
Query 'AS FSH wasn't collected, please remove the time of collection.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 20:14:24
Query 'AS FSH wasn't collected, please remove the time of collection.' answered with 'updated' (Site from CRA).	Ashley Bragg (b) (4)	26 Feb 2021 17:01:06
User entered empty; reason for change Data Entry Error	(b) (4)	
User opened query 'AS FSH wasn't collected, please remove the time of collection.' (Site from CRA).	Ashley Bragg (b) (4)	26 Feb 2021 17:00:36
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 19:51:28
DataPoint Verified.		25 Feb 2021 19:48:47
User entered '09:42'		25 Feb 2021 19:48:17
	Kenadie Hamblin (b) (4)	08 Feb 2021 22:00:09
	(b) (4)	

US3332089

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered empty.	System	26 Feb 2021 17:00:36
User entered '11 Jan 2021 09:42'	System	08 Feb 2021 22:00:09

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:00:39

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:00:39

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:00:39

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'mRNA-1273'	System	08 Feb 2021 22:00:39
DataPoint set to visible.	System	08 Feb 2021 21:54:20

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:00:39

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '10:28'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:00:39

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered '11 Jan 2021 10:28'	System	08 Feb 2021 22:00:39

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:00:39

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:14
User entered 'ONCE'	System	08 Feb 2021 22:00:39

US3332089

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

Form: Exposure

Generated On: 11 Aug 2021 22:21:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 22:00:39

US3332089

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:04:13

US3332089

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:04:13

US3332089

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '09:38'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:04:13

US3332089

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered '11 Jan 2021 09:38'	System	11 Jan 2021 21:04:13

US3332089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:21:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:04:26

US3332089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:21:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11 Jan 2021'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:04:26

US3332089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:21:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '09:35'	(b) (4) Colby Bostock (b) (4) (b) (4)	11 Jan 2021 21:04:26

US3332089

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:21:48

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered '11 Jan 2021 09:35'	System	11 Jan 2021 21:04:26

US3332089

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

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:18:45
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:00:44

US3332089

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

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:00:40
User entered 'I'	System	08 Feb 2021 22:00:44

US3332089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:30
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:19:31
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:45
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:01:08

US3332089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:30
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:19:31
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:45
User entered '18 Jan 2021'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:01:08

US3332089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:30
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:19:31
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:01:08

US3332089

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:21:48

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:30
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:19:31
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:45
User entered empty.	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:01:08

US3332089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:30
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:19:37
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:45
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4) (b) (4)	08 Feb 2021 22:01:15

US3332089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:30
User entered 'I'	System	08 Feb 2021 22:01:15

US3332089

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:21:48

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:30
User entered 'I'	System	08 Feb 2021 22:01:15
DataPoint set to visible.	System	08 Feb 2021 22:01:15

US3332089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:19:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:27:53

US3332089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:19:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:27:53

US3332089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:19:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:27:53

US3332089

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:21:48

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
User entered 'OLD29'	System	09 Feb 2021 19:27:53

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11:05'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
User entered '9 Feb 2021 11:05'	System	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '74'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
User entered 'bpm'	System	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
User entered 'breaths/min'	System	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '112'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
User entered 'mmHg'	System	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '84'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
User entered 'mmHg'	System	09 Feb 2021 19:28:59

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06

US3332089

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:21:48

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06

US3332089

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:29:19

US3332089

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:21:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:29:19

US3332089

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:29:38

US3332089

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:29:38

US3332089

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:20:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '11:08'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:29:38

US3332089

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:21:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:10:06
User entered '9 Feb 2021 11:08'	System	09 Feb 2021 19:29:38

US3332089

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:21:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:00:55
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue, Nausea/Vomiting, Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 03:33:38
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue, Nausea/Vomiting, Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'SUBJECT WAS DIAGNOSED WITH COVID-19 BEGINNING 9.10.20, ae ALREADY CAPTURED COVERING ABOVE SYMPTOMS ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 22:06:32
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue, Nausea/Vomiting, Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 08:48:05

US3332089

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:21:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (22FEB2021) '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)	26 Mar 2021 05:19:46
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (22FEB2021) '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 'Worsening of Insomnia and Worsening of Depression captured as a result of this diary entry. ' (Site from DM).	Kenadie Hamblin (b) (4)	25 Mar 2021 15:12:51
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (22FEB2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 07:18:29
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:21:11
User entered 'Yes (Y)'	Sean Hansen (b) (4)	28 Sep 2020 23:57:08

US3332089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:22:48
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:43
User entered 'USA-US202-2020-mRNA-1273-P301000001'	System	29 Sep 2020 16:19:40
User entered 'New'	(b) (4), (b) (6)	29 Sep 2020 16:19:40

US3332089

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 21:38:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:26
Data point term sent to Coder	System	23 Nov 2020 18:51:21
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	23 Nov 2020 18:51:10
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'entered per sponsor guidance. differentiation between symptomatic or asymptomatic required per sponsor correct as entered ' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 18:51:10
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:24:00
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:22:49
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:49:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 15:49:50
Data point term sent to Coder	System	02 Oct 2020 15:49:14
Coding entries removed.	Ty Henry (b) (4) (b) (4)	02 Oct 2020 15:48:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[Adverse event](#)

Audit	User	Time (GMT)
Signature has been broken.	Ty Henry (b) (4)	02 Oct 2020 15:48:16
	(b) (4)	
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Ty Henry (b) (4)	02 Oct 2020 15:48:16
	(b) (4)	
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 00:06:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 00:06:45
	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 00:05:42
User entered 'Covid-19'	Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:22:50
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:22:53
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered 'No (N)'	Sean Hansen (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:22:55
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:07:47
DataPoint Un-verified.		04 Nov 2020 00:41:51
User entered '18 Sep 2020' reason for change: Data Entry Error		04 Nov 2020 00:41:51
DataPoint Verified.		30 Oct 2020 19:22:57
Signature has been broken.	Ty Henry (b) (4) (b) (4)	16 Oct 2020 19:51:01
User entered '24 Sep 2020' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	16 Oct 2020 19:51:01
User signature succeeded.	James Peterson (b) (4) (b) (4)	30 Sep 2020 22:13:57
User entered '25 Sep 2020'	Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
Query 'Per CDM Requery-Response noted,however, Per CCG, Kindly confirm if Ae started within 24 hours of dosing time,if yes then please consider to add start date else no data is required for start date.Thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:04:44
User opened query 'Per CDM Requery-Response noted,however, Per CCG, Kindly confirm if Ae started within 24 hours of dosing time,if yes then please consider to add start date else no data is required for start date.Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:59:17
Query 'Per CDM Requery-Response noted,however, Per CCG, this field is not required, unless start time is within 24 hours of dosing time, then the field must be completed.Kindly confirm if Ae started within 24 hours of dosing time,if yes then please consider to add start date else no data is required for start date.Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:58:39
User opened query 'Per CDM Requery-Response noted,however, Per CCG, this field is not required, unless start time is within 24 hours of dosing time, then the field must be completed.Kindly confirm if Ae started within 24 hours of dosing time,if yes then please consider to add start date else no data is required for start date.Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:58:24
User closed query 'Per CDM Requery-Response noted, however, as per response 'time updated' but still no data is entered for the field 'start time'.Kindly consider to update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:58:24
Query 'Per CDM Requery-Response noted, however, as per response 'time updated' but still no data is entered for the field 'start time'.Kindly consider to update data appropriately else clarify.' answered with 'added start time again' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:51:26
User entered '21:46' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 18:50:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'Per CDM Requery-Response noted, however, as per response 'time updated' but still no data is entered for the field 'start time'.Kindly consider to update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:22:09
User closed query 'Data is required. Please provide.' (Site from System).		13 Nov 2020 06:16:57
Query 'Data is required. Please provide.' answered with 'PER dm NOT NEEDED' (Site from System).		12 Nov 2020 16:25:57
User opened query 'Data is required. Please provide.' (Site from System).		12 Nov 2020 16:25:46
User entered empty; reason for change New Information		12 Nov 2020 16:25:46
User closed query 'Per CDM-per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17 Sep OCT2020 at 10:48, and AE Start-date is 18 Sep 2020. Please verify data and update AE Start-time as appropriate. Thank you.'" (Site from DM).		11 Nov 2020 08:16:20
Query 'Per CDM-per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17 Sep OCT2020 at 10:48, and AE Start-date is 18 Sep 2020. Please verify data and update AE Start-time as appropriate. Thank you.'" answered with 'time updated' (Site from DM).		10 Nov 2020 17:39:35
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 17:39:24
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:39:24
Signature has been broken.		10 Nov 2020 17:39:24
User entered '19:00' reason for change: New Information		10 Nov 2020 17:39:24
DataPoint Verified.		10 Nov 2020 07:07:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

Start time (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'Per CDM-per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17 Sep OCT2020 at 10:48, and AE Start-date is 18 Sep 2020. Please verify data and update AE Start-time as appropriate. Thank you.'" (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:22:01
User opened query 'Data is required. Please provide.' System (Site from System).		04 Nov 2020 00:41:51
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 21:46'	System	23 Nov 2020 18:50:28
User entered empty.	System	12 Nov 2020 16:25:46
User entered '18 Sep 2020 19:00'	System	10 Nov 2020 17:39:24
User entered empty.	System	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:23:00
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Oct 2020 19:51:28
Signature has been broken.	Ty Henry (b) (4)	16 Oct 2020 19:51:28
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Ty Henry (b) (4)	16 Oct 2020 19:51:28
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Oct 2020 19:51:01
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
	(b) (4)	
User entered 'Yes (Y)'	Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:23:01
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)	19 Oct 2020 18:55:54
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 'Data updated.' (Site from Safety).	Ty Henry (b) (4)	16 Oct 2020 19:51:38
Signature has been broken.	(b) (4)	
	Ty Henry (b) (4)	16 Oct 2020 19:51:01
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Ty Henry (b) (4)	16 Oct 2020 19:51:01
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)	05 Oct 2020 18:15:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered empty.	(b) (4)	
	Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '08:00' reason for change: New Information	(b) (4)	23 Nov 2020 18:50:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 06:18:54
User closed query 'Per CDM re-query: I apologize for the previous query. AE end date is 09Oct2020 which means that end time should not be entered because end date did not ended 24 hours from treatment injection. Please consider removing end time. Thank you!' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:18:50
Query 'Data is required. Please provide.' answered with 'NOT NEEDED PER DM' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 16:26:21
Query 'Per CDM re-query: I apologize for the previous query. AE end date is 09Oct2020 which means that end time should not be entered because end date did not ended 24 hours from treatment injection. Please consider removing end time. Thank you!' answered with 'THANK YOU. DATA REMOVED' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:26:08
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Nov 2020 16:25:46
User entered empty; reason for change New Information	(b) (4), (b) (6)	12 Nov 2020 16:25:46
User opened query 'Per CDM re-query: I apologize for the previous query. AE end date is 09Oct2020 which means that end time should not be entered because end date did not ended 24 hours from treatment injection. Please consider removing end time. Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:18:26
User closed query 'Per CDM-per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17 Sep OCT2020 at 10:48, and AE Start-date is 18 Sep 2020. Please verify data and update AE Start-timeand also Ae end time as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:16:58

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Folder: Adverse Events

Form: Adverse Events (1)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Query 'Per CDM-per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17 Sep OCT2020 at 10:48, and AE Start-date is 18 Sep 2020. Please verify data and update AE Start-timeand also Ae end time as appropriate. Thank you.'"	(b) (4), (b) (6)	10 Nov 2020 17:39:41
answered with 'time updated' (Site from DM). User closed query 'Data is required. Please provide.' (Site from System).	System	10 Nov 2020 17:39:24
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:39:24
Signature has been broken.		10 Nov 2020 17:39:24
User entered '08:00' reason for change: New Information		10 Nov 2020 17:39:24
DataPoint Verified.		10 Nov 2020 07:07:47
User opened query 'Per CDM-per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 17 Sep OCT2020 at 10:48, and AE Start-date is 18 Sep 2020. Please verify data and update AE Start-timeand also Ae end time as appropriate. Thank you.'"		06 Nov 2020 06:19:31
(Site from DM). User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 00:41:51
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered empty.	(b) (4)	
	Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 08:00'	System	23 Nov 2020 18:50:28
User entered empty.	System	12 Nov 2020 16:25:46
User entered '09 Oct 2020 08:00'	System	10 Nov 2020 17:39:24
User entered empty.	System	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:23:06
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:23:08
Signature has been broken.	Ty Henry (b) (4)	02 Oct 2020 15:48:16
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Ty Henry (b) (4)	02 Oct 2020 15:48:16
	(b) (4)	
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Grimmatt (b) (4)	30 Sep 2020 18:40:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 00:06:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 00:06:51
User entered 'No (N)' reason for change: Data Entry Error	Sean Hansen (b) (4)	29 Sep 2020 00:06:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 00:05:34
User entered empty.	Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered '0'	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered '0'	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered '0'	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered empty.	Sean Hansen (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered '0'	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered '0'	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:07:47
Signature has been broken.	Ty Henry (b) (4)	02 Oct 2020 15:48:16
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Ty Henry (b) (4)	02 Oct 2020 15:48:16
	(b) (4)	
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Megan Grimmatt (b) (4)	30 Sep 2020 18:40:39
	(b) (4)	
User entered '0'	Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:23:12
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	30 Sep 2020 21:40:31
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	29 Sep 2020 00:06:39
User entered 'Not Related (NOT RELATED)'	Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:23:14
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered 'Not Related (NOT RELATED)'	Sean Hansen (b) (4)	29 Sep 2020 00:05:34

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 07:30:53
User closed query 'Per CDM: since Investigational Product Withdrawn, please consider completing Dosing Discontinuation form at End of Study visit.' (Site from DM).		13 Nov 2020 07:29:48
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'reason documented as sars-cov-02' (Site from System).		10 Nov 2020 17:32:14
Query 'Per CDM: since Investigational Product Withdrawn, please consider completing Dosing Discontinuation form at End of Study visit.' answered com1) with 'done' (Site from DM).		10 Nov 2020 17:31:45
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	04 Nov 2020 00:42:16
User opened query 'Per CDM: since Investigational Product Withdrawn, please consider completing Dosing Discontinuation form at End of Study visit.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:43:14
DataPoint Verified.		30 Oct 2020 19:23:18
User closed query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or clarify otherwise. Thank you!' (Site from DM).		27 Oct 2020 06:26:22

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Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or clarify otherwise. Thank you!" answered with 'Subject is being followed for safety per protocol.' (Site from DM).	Sean Hansen (b) (4) (b) (4)	26 Oct 2020 22:40:43
User opened query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however "End of Study" forms are not completed. Please consider completing "End of Study" forms or clarify otherwise. Thank you!" (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:10:16
User signature succeeded.	James Peterson (b) (4) (b) (4)	30 Sep 2020 22:13:57
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 00:06:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 00:06:39
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:06:39
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 00:05:34
User entered empty.	Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered '0'	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered 'I'	Sean Hansen (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered '0'	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:25:01
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.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:27:55
Signature has been broken.	Ty Henry (b) (4)	16 Oct 2020 19:51:01
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Ty Henry (b) (4)	16 Oct 2020 19:51:01
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:15:32
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sean Hansen (b) (4)	29 Sep 2020 00:05:34
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User closed query 'Per protocol (Section 8.3.7): "All confirmed COVID-19 cases and SAEs will be recorded and reported to the Sponsor or designee immediately and under no circumstance should this exceed 24 hours"	(b) (4), (b) (6)	02 Nov 2020 16:33:54
Confirmed COVID-19 cases, won't reported as SAE, unless subject meets the definition of an SAE (hospitalization,...). Please verify the Narrative. ' (Site from CRA).		
Query 'Per protocol (Section 8.3.7): "All confirmed COVID-19 cases and SAEs will be recorded and reported to the Sponsor or designee immediately and under no circumstance should this exceed 24 hours"	(b) (4), (b) (6)	30 Oct 2020 23:39:25
Confirmed COVID-19 cases, won't reported as SAE, unless subject meets the definition of an SAE (hospitalization,...). Please verify the Narrative. ' answered with 'updated' (Site from CRA).		
Signature has been broken.	(b) (4), (b) (6)	30 Oct 2020 23:39:13
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 23:39:13
User opened query 'Per protocol (Section 8.3.7): "All confirmed COVID-19 cases and SAEs will be recorded and reported to the Sponsor or designee immediately and under no circumstance should this exceed 24 hours"	(b) (4), (b) (6)	30 Oct 2020 19:47:31
Confirmed COVID-19 cases, won't reported as SAE, unless subject meets the definition of an SAE (hospitalization,...). Please verify the Narrative. ' (Site from CRA).		
User closed query 'PV Query: Please provide result of blood sample taken for immunologic assessment of SARS_COV-2 Infection from 25 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:41:39

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The subject was given Theraflu for the event, from 21 Sep 2020 to 26 Sep 2020; however, the event onset date is given as 24 Sep 2020. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:41:35
User closed query 'PV Query: Please confirm the result for the nasopharyngeal swab on 17 Sep and the type of test.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:41:20
User closed query 'PV Query: Please confirm if physical examination was normal.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 16:41:14
Query 'PV Query: Please provide result of blood sample taken for immunologic assessment of SARS_COV-2 Infection from 25 Sep 2020.' answered with 'Blood sample results are not provided to the site.' (Site from Safety).	Sean Hansen (b) (4) (b) (4)	26 Oct 2020 22:59:52
Query 'PV Query: The subject was given Theraflu for the event, from 21 Sep 2020 to 26 Sep 2020; however, the event onset date is given as 24 Sep 2020. Please clarify.' answered with 'Updated start date to 24 Sep 2020.' (Site from Safety).	Sean Hansen (b) (4) (b) (4)	26 Oct 2020 22:45:37
Query 'PV Query: Please confirm the result for the nasopharyngeal swab on 17 Sep and the type of test.' answered with 'Confirmed nasal swab from 9/17/20 was negative.' (Site from Safety).	Sean Hansen (b) (4) (b) (4)	26 Oct 2020 22:44:53
Query 'PV Query: Please confirm if physical examination was normal.' answered with 'Confirmed physical exam was normal.' (Site from Safety).	Sean Hansen (b) (4) (b) (4)	26 Oct 2020 22:43:52
User opened query 'PV Query: Please provide result of blood sample taken for immunologic assessment of SARS_COV-2 Infection from 25 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:31:00
User opened query 'PV Query: The subject was given Theraflu for the event, from 21 Sep 2020 to 26 Sep 2020; however, the event onset date is given as 24 Sep 2020. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:30:38
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.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:30:27

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide result of blood sample taken for immunologic assessment of SARS_COV-2 Infection from 25 Sep 2020.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:30:16
Query 'PV Query: Please confirm the test date for SARS-COV-2 as the onset date is a day later.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:30:07
User opened query 'PV Query: Please provide result of blood sample taken for immunologic assessment of SARS_COV-2 Infection from 25 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:16:54
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)	05 Oct 2020 18:15:44
User opened query 'PV Query: Please confirm the result for the nasopharyngeal swab on 17 Sep and the type of test.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:14:58
User opened query 'PV Query: Please confirm if physical examination was normal.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:14:46
User opened query 'PV Query: Please confirm the test date for SARS-COV-2 as the onset date is a day later.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 18:14:37
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:57
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	30 Sep 2020 18:41:17
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 18:41:17
User entered 'Per amendment 3, confirmed COVID-19 diagnosis reported as SAE' reason for change: Data Entry Error	Megan Grimmatt (b) (4) (b) (4)	30 Sep 2020 18:41:17
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Sep 2020 18:40:39

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[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Sean Hansen (b) (4) (b) (4)	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 15:48:16
User entered '1'	System	30 Sep 2020 18:40:39
User entered '0'	System	29 Sep 2020 00:06:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Sep 2020 00:05:34

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:07:47
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Stomach pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:33:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:33:44
Data point term sent to Coder	System	29 Oct 2020 20:33:19
User entered 'STOMACH PAIN'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:07:47
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:07:47
User entered '30 Sep 2020'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User entered empty.	System	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered '2 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User entered empty.	System	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:07:47
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:07:47
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:33:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 20:33:27
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:33:27
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:45
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:07:47
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Oct 2020 20:33:27
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Oct 2020 20:32:45
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:33:27
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:07:47
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	10 Nov 2020 07:07:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:07:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User entered '0'	System	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40
User entered '0'	System	29 Oct 2020 20:32:45

US3332089

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:21:48

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User closed query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 05:19:00
Query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. ' answered with 'Updated baseline medical history ' (Site from DM).	Kenadie Hamblin (b) (4)	25 Mar 2021 15:11:02
User opened query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 06:15:53
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User coded data point as SOC: Psychiatric disorders, HLG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia exacerbated - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	26 Feb 2021 15:15:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Feb 2021 15:15:52
Data point term sent to Coder	System	26 Feb 2021 15:14:48
User entered 'Worsening of Insomnia'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'No (N)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'No (N)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '12 Feb 2021'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'No (N)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'I'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 15:13:58

US3332089

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:21:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 15:13:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:16:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 15:16:52
Data point term sent to Coder	System	26 Feb 2021 15:15:50
User entered 'Worsening of Depression'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'No (N)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'No (N)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '23 Jan 2021'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'No (N)'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

US3332089

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'I'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered '0'	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:45:36
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:28:23
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:21:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 15:15:21

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:54:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 21:54:28
Data point term sent to Coder	System	19 Apr 2021 21:51:24
User entered 'COVID-like illness'	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'Yes (Y)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '13 Apr 2021'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered empty.	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '17 Apr 2021'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered empty.	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '0'	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '0'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '0'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered empty.	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered empty.	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered empty.	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered empty.	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '0'	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '0'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '0'	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'Not Applicable (NOT APPLICABLE)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'I'	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '0'	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered '0'	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered empty.	Ashley Bragg (b) (4) (b) (4)	19 Apr 2021 21:50:24

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:43:58
User entered empty.	Ashley Bragg (b) (4)	19 Apr 2021 21:50:24
	(b) (4)	

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 21:50:24

US3332089

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:21:48

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 21:50:24

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:00:55
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:49:20
User closed query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 08:10:58
Query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' answered with 'Medication Updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:26:22
User opened query 'Per CDM: According to a "Diary Dose 1", medication was taken to treat pain or fever, however no corresponding CM is entered. Please consider entering corresponding CM or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:32:43
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:51:46

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:49:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:53:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:53:43
Data point term sent to Coder	System	17 Sep 2020 17:53:22
User entered 'Bupropion'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:49:54
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:49:56
User entered 'Depression'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:49:58
User entered '300'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:50:00
User entered 'mg (mg)'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:50:06
User entered 'once daily (QD)'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:50:09
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:50:11
User entered 'un UNK 2005'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:50:18
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:50:27
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:52:50
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:52:50

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:51:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:54:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:54:44
Data point term sent to Coder	System	17 Sep 2020 17:54:24
User entered 'Duloxetine'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:51:24
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:53:34
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:51:26
User entered 'Depression'	Ty Henry (b) (4)	17 Sep 2020 17:53:34
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:51:27
User entered '120'	Ty Henry (b) (4)	17 Sep 2020 17:53:34
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:51:30
User entered 'mg (mg)'	Ty Henry (b) (4)	17 Sep 2020 17:53:34
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:51:32
User entered 'once daily (QD)'	Ty Henry (b) (4)	17 Sep 2020 17:53:34
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:51:34
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	17 Sep 2020 17:53:34
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:51:41
User entered 'un UNK 2015'	Ty Henry (b) (4)	17 Sep 2020 17:53:34
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4)	17 Sep 2020 17:53:34
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:51:44
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:51:47
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:53:34

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:52:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:52:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:52:46
Data point term sent to Coder	System	17 Sep 2020 17:54:24
User entered 'Glucosamine'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:52:07
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:54:09
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:52:13
User entered 'Bilateral Knee Pain'	Ty Henry (b) (4)	17 Sep 2020 17:54:09
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 11:44:01
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:02:14
DataPoint Un-verified.		10 Nov 2020 17:01:39
User entered '1500' reason for change: Per Query Resolution		10 Nov 2020 17:01:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).		06 Nov 2020 10:46:13
DataPoint Verified.		30 Oct 2020 19:52:22
User entered '1'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:01:39
User entered 'mg (mg)' reason for change: Per Query Resolution		10 Nov 2020 17:01:39
DataPoint Verified.		30 Oct 2020 19:52:24
User entered 'tablet (TABLET)'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:52:27
User entered 'once daily (QD)'	Ty Henry (b) (4)	17 Sep 2020 17:54:09
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:52:30
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	17 Sep 2020 17:54:09
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:12:34
User closed query 'Per source, data corrected to UNUNK2012, Please verify. ' (Site from CRA).		02 Nov 2020 16:34:58
Query 'Per source, data corrected to UNUNK2012, Please verify. ' answered with 'updated' (Site from CRA).		30 Oct 2020 23:40:56
User entered 'UN UNK 2012' reason for change: Data Entry Error		30 Oct 2020 23:40:51
User opened query 'Per source, data corrected to UNUNK2012, Please verify. ' (Site from CRA).		30 Oct 2020 19:54:39
User entered 'un UNK 2010'	Ty Henry (b) (4)	17 Sep 2020 17:54:09
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:54:55
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Sep 2020 17:54:09
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:54:58
User entered 'No (N)'	Ty Henry (b) (4)	17 Sep 2020 17:54:09
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:54:09

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:55:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:44:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:44:21
Data point term sent to Coder	System	06 Oct 2020 15:43:55
User entered 'Tylenol'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:55:16
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per DM: No AE matches indication for this CONMED. Please confirm that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 11:37:54
Query 'Per DM: No AE matches indication for this CONMED. Please confirm that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'doesn't meet criteria for unsolicited AE ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:15:07
User opened query 'Per DM: No AE matches indication for this CONMED. Please confirm that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:32:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:32:48

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'reported correctly ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:29:28
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:50:12
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:55:26
User entered 'Injection Site Pain, Muscle Aches'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:55:24
User entered '100'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:55:28
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:55:42
User entered 'as needed (PRN)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:55:44
User entered 'Oral (ORAL)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:55:46
User entered '18 Sep 2020'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:56:00
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:57:21
User entered '26 Sep 2020'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 01:42:31
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:57:22
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria. ' answered with 'solicited AE correct as entered ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:19:00

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN, MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Ty Henry (b) (4) (b) (4)	30 Oct 2020 12:15:50 06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User entered empty.	System	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User entered empty.	System	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:25
User entered empty.	System	06 Oct 2020 15:43:32

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:59:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 17:49:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 17:49:22
Data point term sent to Coder	System	26 Oct 2020 22:21:24
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	26 Oct 2020 22:21:17
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'updated per query' (Site from System).	Sean Hansen (b) (4)	26 Oct 2020 22:21:17
User entered 'THERAFLU (Acetaminophen, Diphenhydramine, Phenylephrine)' reason for change: Data Entry Error	Sean Hansen (b) (4)	26 Oct 2020 22:21:08
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	12 Oct 2020 14:25:18
Data point term sent to Coder	System	06 Oct 2020 15:58:42
User entered 'Theraflu'	Ty Henry (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:59:20
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:59:41
User entered 'Symptomatic Covid-19'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:59:44
User entered 'l'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:00:06
User entered 'Other (OTHER)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:00:08
User entered 'Packet'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:00:10
User entered 'as needed (PRN)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:00:13
User entered 'Oral (ORAL)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 20:00:23
User entered '24 Sep 2020' reason for change: Data Entry Error	Sean Hansen (b) (4)	26 Oct 2020 22:13:29
User entered '21 Sep 2020'	Ty Henry (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:00:24
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:00:26
User entered '26 Sep 2020'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:00:28
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User entered empty.	System	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User entered empty.	System	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:32
User entered empty.	System	06 Oct 2020 15:58:03

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:01:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: CAFFEINE;MEPYRAMINE MALEATE;PARACETAMOL, PRODUCTSYNONYM: MIDOL [CAFFEINE;MEPYRAMINE MALEATE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 17:43:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 17:43:07
Data point term sent to Coder	System	26 Oct 2020 22:28:31
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	26 Oct 2020 22:28:14
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated per query' (Site from System).	Sean Hansen (b) (4)	26 Oct 2020 22:28:14
User entered 'MIDOL (Acetaminophen, Caffeine, Pylramine)' reason for change: Data Entry Error	Sean Hansen (b) (4)	26 Oct 2020 22:27:59
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	09 Oct 2020 14:24:20
Data point term sent to Coder	System	06 Oct 2020 15:59:44

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Midol'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:01:06
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:01:14
User entered 'Stomach Pain'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:01:35
User entered '2'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:01:36
User entered 'capsule (CAPSULE)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:01:39
User entered 'as needed (PRN)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:01:41
User entered 'Oral (ORAL)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:01:43
User entered '30 Sep 2020'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
DataPoint Un-verified.		09 Nov 2020 21:16:47
User entered 'No (N)' reason for change: Data Entry Error		09 Nov 2020 21:16:47
DataPoint Verified.		30 Oct 2020 20:01:46
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per CDM-Kindly consider to update conmed end date since corresponding ae ended on 02 oct 2020.Please consider to update accordingly else clarify.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 11:39:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:12:34
Query 'Per CDM-Kindly consider to update conmed end date since corresponding ae ended on 02 oct 2020.Please consider to update accordingly else clarify.Thank you.' answered with 'ty' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:16:55
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		09 Nov 2020 21:16:47
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Nov 2020 21:16:37
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 21:16:37
User opened query 'Per CDM-Kindly consider to update conmed end date since corresponding ae ended on 02 oct 2020.Please consider to update accordingly else clarify.Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:24:31
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 20:01:47
User entered 'No (N)'	Ty Henry (b) (4)	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User entered empty.	System	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User entered empty.	System	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:20:56
User entered empty.	System	06 Oct 2020 15:59:10

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:02:01
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)	06 Oct 2020 16:21:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
	(b) (4)	06 Oct 2020 16:21:26
Data point term sent to Coder	System	06 Oct 2020 16:19:47
User entered 'Mirena'	Ty Henry (b) (4)	06 Oct 2020 16:19:27
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:02:03
User entered 'Yes (Y)'	Ty Henry (b) (4)	06 Oct 2020 16:19:27
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:02:05
User entered 'Pregnancy Prophylaxis'	Ty Henry (b) (4)	06 Oct 2020 16:19:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User closed query 'per source, dosage is 200 ug. please verify.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:13:41 10 Mar 2021 20:13:38
Query 'per source, dosage is 200 ug. please verify.' answered with 'UPDATED' (Site from CRA). Signature has been broken.		26 Feb 2021 18:29:56 26 Feb 2021 18:29:49
User entered '200' reason for change: Data Entry Error DataPoint Un-verified.		26 Feb 2021 18:29:49 25 Feb 2021 20:58:18
DataPoint Verified.		25 Feb 2021 20:57:57
User opened query 'per source, dosage is 200 ug. please verify.' (Site from CRA). User signature succeeded.	James Peterson (b) (4)	25 Feb 2021 20:25:56 23 Feb 2021 13:36:30
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg. 20 ug) or provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg. 20 ug) or provide explanation for alternate dosage.' answered with 'dosage updated' (Site from DM). User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) Megan Grimmatt (b) (4) (b) (4) Megan Grimmatt (b) (4)	15 Dec 2020 05:26:05 14 Dec 2020 22:57:24 14 Dec 2020 22:55:56
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage (eg. 20 ug) or provide explanation for alternate dosage.' (Site from DM). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 21:21:29 12 Nov 2020 16:27:34
User entered '200' reason for change: Data Entry Error DataPoint Verified.		12 Nov 2020 16:27:34 30 Oct 2020 20:02:11

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:19:27

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:48
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	26 Feb 2021 18:30:55
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	26 Feb 2021 18:29:49
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 18:29:49
User entered 'ug (ug)' reason for change: Data Entry Error		26 Feb 2021 18:29:49
DataPoint Un-verified.		25 Feb 2021 20:58:23
DataPoint Verified.		25 Feb 2021 20:57:57
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) Megan Grimmatt (b) (4)	14 Dec 2020 22:55:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:34
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 16:27:34
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:02:13
User entered 'Other (OTHER)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:19:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:58:48
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:30:55
Signature has been broken.		26 Feb 2021 18:30:55
User entered empty; reason for change Data Entry Error		26 Feb 2021 18:30:55
DataPoint Verified.		25 Feb 2021 20:57:57
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'Device' reason for change: Data Entry Error	(b) (4) Megan Grimmatt (b) (4)	14 Dec 2020 22:55:56
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:34
User entered empty; reason for change Data Entry Error		12 Nov 2020 16:27:34
DataPoint Verified.		30 Oct 2020 20:02:39
User entered 'Device'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:19:27

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'PER CDM CLR Requery-mirena is a IUD in which is inserted "ONCE" in route of "Intrauterine" , medication is on going. the frequency can not be daily because the subject is not inserting a new IUD everyday'.Kindly consider to verify and update data appropriately else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 05:42:29
Query 'PER CDM CLR Requery-mirena is a IUD in which is inserted "ONCE" in route of "Intrauterine" , medication is on going. the frequency can not be daily because the subject is not inserting a new IUD everyday'.Kindly consider to verify and update data appropriately else clarify.' answered with 'updated' (Site from DM).	Colby Bostock (b) (4) (b) (4)	18 Jan 2021 17:48:49
User entered 'once (ONCE)' reason for change: Data Entry Error	Colby Bostock (b) (4) (b) (4)	18 Jan 2021 17:48:43
User opened query 'PER CDM CLR Requery-mirena is a IUD in which is inserted "ONCE" in route of "Intrauterine" , medication is on going. the frequency can not be daily because the subject is not inserting a new IUD everyday'.Kindly consider to verify and update data appropriately else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 08:53:14
User closed query 'Per CDM CLR re-query: Please review frequency recorded as 'once daily' .Either update frequency or provide end date. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 08:53:14
Query 'Per CDM CLR re-query: Please review frequency recorded as 'once daily' .Either update frequency or provide end date. Thank you!' answered with 'correct as entered, please clarify what is preferred dosing to be entered' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:38:21
User opened query 'Per CDM CLR re-query: Please review frequency recorded as 'once daily' .Either update frequency or provide end date. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 05:25:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CLR re-query: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Thank you!' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:38:53
Query 'Per CDM CLR re-query: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Thank you!' answered with '.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:27:40
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:34
User entered 'once daily (QD)' reason for change: Data Entry Error		12 Nov 2020 16:27:34
User opened query 'Per CDM CLR re-query: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Thank you!' (Site from DM).		11 Nov 2020 11:53:09
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.		11 Nov 2020 11:52:47
' (Site from DM).		
Query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.		10 Nov 2020 17:08:56
' answered with 'iud is only inserted one time, correct as is' (Site from DM).		
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.		06 Nov 2020 10:49:09
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:02:41
User entered 'once (ONCE)'	Ty Henry (b) (4)	06 Oct 2020 16:19:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:19:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:02:47
User entered 'Other (OTHER)'	Ty Henry (b) (4)	06 Oct 2020 16:19:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:02:49
User entered 'Intrauterine'	Ty Henry (b) (4)	06 Oct 2020 16:19:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:03:18
User entered 'un Jul 2016'	Ty Henry (b) (4)	06 Oct 2020 16:19:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4)	06 Oct 2020 16:19:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:03:20
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:19:27

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:19:27

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:03:23
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:19:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 17:48:43
User entered '1'	System	12 Nov 2020 16:27:34
User entered empty.	System	06 Oct 2020 16:19:27

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 17:48:43
User entered '1'	System	12 Nov 2020 16:27:34
User entered empty.	System	06 Oct 2020 16:19:27

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 17:48:43
User entered '804 (804)'	System	12 Nov 2020 16:27:34
User entered empty.	System	06 Oct 2020 16:19:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:03:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:48:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:48:23
Data point term sent to Coder	System	06 Oct 2020 16:22:52
User entered 'Oxycodone'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:03:41
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:03:47
User entered 'Symptomatic Covid-19'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:03:54
User entered '5'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:03:56
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:03:58
User entered 'as needed (PRN)'	Ty Henry (b) (4)	06 Oct 2020 16:22:28
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:03:59
User entered 'Oral (ORAL)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:04:07
User entered '03 Oct 2020'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:04:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:35:29
User entered 'Yes (Y)'	Ty Henry (b) (4)	06 Oct 2020 16:22:28
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	30 Oct 2020 20:04:12
User entered '3 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:35:29
User entered empty.	Ty Henry (b) (4)	06 Oct 2020 16:22:28
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:04:36
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User entered empty.	System	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User entered empty.	System	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:03
User entered empty.	System	06 Oct 2020 16:22:28

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:05:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:25:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:25:21
Data point term sent to Coder	System	06 Oct 2020 16:23:54
User entered 'Norco'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:05:50
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:05:54
User entered 'Injection Site Pain'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query ""	(b) (4) (b) (4), (b) (6)	11 Nov 2020 13:44:12
Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125)." ' (Site from DM). Query ""	(b) (4), (b) (6)	10 Nov 2020 17:10:46
Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125)." ' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:10:27
User entered '5/325' reason for change: Data Entry Error		10 Nov 2020 17:10:27
User opened query ""		06 Nov 2020 10:49:36
Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125)." ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:05:56
User entered '325'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:05:57
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:15
User entered 'once (ONCE)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:17
User entered 'Oral (ORAL)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:19
User entered '18 Sep 2020'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:21
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:23
User entered '18 Sep 2020'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per CDM: There is no AE that matches this Con Med indication. Please review and confirm that the solicited adverse event reaction of Injection Site Pain did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:37:36
Query 'Per CDM: There is no AE that matches this Con Med indication. Please review and confirm that the solicited adverse event reaction of Injection Site Pain did not meet the AE reporting criteria. ' answered with 'taken for solicited ae as reported in diary. does not meet ae reporting criteria. correct as is' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:13:12
User opened query 'Per CDM: There is no AE that matches this Con Med indication. Please review and confirm that the solicited adverse event reaction of Injection Site Pain did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:45:20
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:45:20
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:06:26

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'solicited reaction AE should not be double captured ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:20:07
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:16:46
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User entered empty.	System	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User entered empty.	System	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:08
User entered empty.	System	06 Oct 2020 16:23:39

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:27:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:27:17
Data point term sent to Coder	System	06 Oct 2020 16:26:57
User entered 'Tylenol'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:43
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:54
User entered 'Symptomatic Covid-19'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:56
User entered '200'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:57
User entered 'mg (mg)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:06:59
User entered 'as needed (PRN)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:07:01
User entered 'Oral (ORAL)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered empty.	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 20:07:15
User entered '24 Sep 2020'	Ty Henry (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:12:34
User entered '0'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:07:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:35:04
User entered 'Yes (Y)'	Ty Henry (b) (4)	06 Oct 2020 16:25:58
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:07:20
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:35:04
User entered empty.	Ty Henry (b) (4)	06 Oct 2020 16:25:58
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:07:22
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User entered empty.	System	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User entered empty.	System	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:21:14
User entered empty.	System	06 Oct 2020 16:25:58

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 20:50:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 20:50:00
	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 20:48:57
User entered 'AMBIEN'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'No (N)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'INSOMNIA'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered '5'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'mg (mg)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered empty.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'as needed (PRN)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered empty.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'Oral (ORAL)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered empty.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered '12 Feb 2021'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered '0'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered empty.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'No (N)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:48:46
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:48:46

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:48:46

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 20:48:46

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 20:51:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 20:51:02
	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 20:49:59
User entered 'LEXAPRO'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'No (N)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'DEPRESSION'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered '10'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'mg (mg)'	Kenadie Hamblin (b) (4) (b) (4)	25 Feb 2021 20:49:42

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered empty.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'once daily (QD)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered empty.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'Oral (ORAL)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered empty.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered '12 Feb 2021'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered '0'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered empty.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:15:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 20:57:57
User entered 'No (N)'	Kenadie Hamblin (b) (4)	25 Feb 2021 20:49:42
	(b) (4)	

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 20:49:42

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 20:49:42

US3332089

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:21:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 20:49:42

US3332089

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:21:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:34:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 00:33:01

US3332089

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:21:48

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:59:52
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 00:42:16

US3332089

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:21:48

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:59:52
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User closed query 'Per CDM: Please confirm if subject continues on follow-up or not. If not, then please consider entering data also under "End of Study/Study discontinuation". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:01:24
Query 'Per CDM: Please confirm if subject continues on follow-up or not. If not, then please consider entering data also under "End of Study/Study discontinuation". Thank you!' answered with 'subject will continue for safety f/u but not for dosing per protocol ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:29:42
User opened query 'Per CDM: Please confirm if subject continues on follow-up or not. If not, then please consider entering data also under "End of Study/Study discontinuation". Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:13:32
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	04 Nov 2020 00:42:16

US3332089

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:21:48

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:59:52
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 00:42:16

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'USA-US202-2020-MRNA-1273-P301000001'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'James'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'Peterson'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '2295 S Foothill Drive'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'SLC'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'UT'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '84109'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered 'US'	(b) (4) System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
User entered '5'	System	27 Oct 2020 16:48:40
User entered '4'	System	19 Oct 2020 18:57:26
User entered '3'	System	02 Oct 2020 17:25:23
Signature has been broken.	System	01 Oct 2020 15:53:14
User entered '2'	System	01 Oct 2020 15:53:14
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'USA-US202-2020-MRNA-1273-P301000001'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'James'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'Peterson'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '2295 S Foothill Drive'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'SLC'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'UT'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '84109'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered 'US'	(b) (4) System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
User entered '5'	System	27 Oct 2020 16:48:40
User entered '4'	System	19 Oct 2020 18:57:26
User entered '3'	System	02 Oct 2020 17:25:23
Signature has been broken.	System	01 Oct 2020 15:53:14
User entered '2'	System	01 Oct 2020 15:53:14
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:21:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered '29/Sep/2020 12:20'	(b) (4) System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:21:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'USA-US202-2020-MRNA-1273-P301000001'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'James'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'Peterson'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	
	System	30 Sep 2020 18:40:39
User entered '2295 S Foothill Drive'	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'SLC'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'UT'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '84109'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered 'US'	(b) (4) System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
User entered '5'	System	27 Oct 2020 16:48:40
User entered '4'	System	19 Oct 2020 18:57:26
User entered '3'	System	02 Oct 2020 17:25:23
Signature has been broken.	System	01 Oct 2020 15:53:14
User entered '2'	System	01 Oct 2020 15:53:14
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:21:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:06:10
User entered '01/Oct/2020 15:53'	System	01 Oct 2020 15:53:14

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:21:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 15:53:14

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'USA-US202-2020-MRNA-1273-P301000001'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'James'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'Peterson'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '2295 S Foothill Drive'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'SLC'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'UT'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '84109'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered 'US'	(b) (4) System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
User entered '5'	System	27 Oct 2020 16:48:40
User entered '4'	System	19 Oct 2020 18:57:26
User entered '3'	System	02 Oct 2020 17:25:23
Signature has been broken.	System	01 Oct 2020 15:53:14
User entered '2'	System	01 Oct 2020 15:53:14
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:21:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:06:10
User entered '02/Oct/2020 13:25'	System	02 Oct 2020 17:25:23

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:21:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 18:57:02
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 17:25:23

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'USA-US202-2020-MRNA-1273-P301000001'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'James'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'Peterson'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '2295 S Foothill Drive'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'SLC'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'UT'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '84109'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered 'US'	(b) (4) System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
User entered '5'	System	27 Oct 2020 16:48:40
User entered '4'	System	19 Oct 2020 18:57:26
User entered '3'	System	02 Oct 2020 17:25:23
Signature has been broken.	System	01 Oct 2020 15:53:14
User entered '2'	System	01 Oct 2020 15:53:14
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:21:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:06:10
User entered '19/Oct/2020 14:57'	System	19 Oct 2020 18:57:26

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:21:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 16:48:23
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 18:57:26

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'USA-US202-2020-MRNA-1273-P301000001'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
Signature has been broken.	System	02 Oct 2020 15:48:16
User entered 'No (N)'	System	02 Oct 2020 15:48:16
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
Un-reviewed for Safety.	System	30 Sep 2020 18:40:39
User entered 'Yes (Y)'	System	30 Sep 2020 18:40:39
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'No (N)'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'James'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 16:19:56
User entered 'Peterson'	System	29 Sep 2020 16:19:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '2295 S Foothill Drive'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'SLC'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered 'UT'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered empty.	(b) (4)	30 Sep 2020 18:40:39
User entered '84109'	System	30 Sep 2020 18:40:39
	Megan Grimmett (b) (4)	30 Sep 2020 18:38:55
	(b) (4)	

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 07:06:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:25:13
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
User entered 'US'	(b) (4) System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:21:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
	(b) (4)	
User entered '5'	System	27 Oct 2020 16:48:40
User entered '4'	System	19 Oct 2020 18:57:26
User entered '3'	System	02 Oct 2020 17:25:23
Signature has been broken.	System	01 Oct 2020 15:53:14
User entered '2'	System	01 Oct 2020 15:53:14
User signature succeeded.	James Peterson (b) (4)	30 Sep 2020 22:13:38
	(b) (4)	
User entered '1'	System	29 Sep 2020 16:20:04

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:21:48

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 07:06:10
User entered '27/Oct/2020 16:48'	System	27 Oct 2020 16:48:40

US3332089

Folder: SAE USA-US202-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:21:48

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:36:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 07:06:10
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 16:48:40