

US3332001 (Prod: Foothill Family Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:08:14

All time stamps listed in this document are displayed in GMT

US3332001

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 13:27:42

Generated On: 09 Jun 2021 17:08:14

[Participant ID](#)

US3332001

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

US3332001

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3332001

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

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 18:04:37

Generated On: 09 Jun 2021 17:08:14

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	31 OCT 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)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Condition	LOW TESTOSTERONE
Start date (dd MMM yyyy)	29 NOV 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Condition	ALCOHOLISM
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

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: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Condition	HYPERTENSION
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)	_____

US3332001

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:10 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 16:10
Height (<i>xxx.x</i>)	70.0 in
Weight (<i>xxx.x</i>)	145.0 lb
BMI (<i>xxx.x</i>)	20.84884 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 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:04:37

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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 True

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 18:04:37

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

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

Visit date (dd MMM yyyy)	03 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

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

What was the participant's randomization number? 184583

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

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 18:04:37

Generated On: 09 Jun 2021 17:08:14

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)	3 AUG 2020
Time of assessment (00:00-23:59)	16:10 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 16:10
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)	89 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)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	3 AUG 2020
Time of assessment (00:00-23:59)	17:55 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 17:55
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3332001

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

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.

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 03 AUG 2020

What was the treatment time? (00:00-23:59) 17:22 (24 HR)

Treatment Date and Time (derived) 03 AUG 2020 17:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 AUG 2020

Collection time (00:00-23:59)

16:30 (24 HR)

Collection date and time (derived)

3 AUG 2020 16:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Collection date (dd MMM yyyy)			3 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:45	3 AUG 2020 16:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 17:56

PC Open Date & Time

03 AUG 2020 17:42

PC Close Date & Time

03 AUG 2020 20:12

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 97.4 °F

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

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

PC Time Stamp	03 AUG 2020 22:13
PC Open Date & Time	03 AUG 2020 21:07
PC Close Date & Time	04 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 12:06

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 06:02

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

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

96.3 °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

06 AUG 2020 12:25

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:44

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:17

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 12:24

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 17:57

PC Open Date & Time

03 AUG 2020 17:42

PC Close Date & Time

03 AUG 2020 20:12

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 22:14

PC Open Date & Time

03 AUG 2020 21:07

PC Close Date & Time

04 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 12:07

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

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

06 AUG 2020 06:03

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 12:26

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 12:44

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 12:17

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:25

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 17:57
PC Open Date & Time	03 AUG 2020 17:42
PC Close Date & Time	03 AUG 2020 20:12

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 22:16
PC Open Date & Time	03 AUG 2020 21:07
PC Close Date & Time	04 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 12:08
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2792

EAB) (1725)

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 06:03
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 12:26
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

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 ☒

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 12:45
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2792

EAB) (1725)

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:18
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2792

EAB) (1725)

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 12:26
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3332001

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

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)	28 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 13:50
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)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

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)	28 AUG 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:20
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3332001

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 14:42 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 14:42

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

US3332001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

14:14 (24 HR)

Collection date and time (derived)

28 AUG 2020 14:14

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:10	28 AUG 2020 14:10
Nasopharyngeal Swab 2	No		

US3332001

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 15:15

PC Open Date & Time

28 AUG 2020 15:02

PC Close Date & Time

28 AUG 2020 17:32

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.3 °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	29 AUG 2020 11:12
PC Open Date & Time	28 AUG 2020 18:27
PC Close Date & Time	29 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 00:01

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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 30 AUG 2020 12:01

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

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

31 AUG 2020 12:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 15:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:48

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 16:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 15:16

PC Open Date & Time

28 AUG 2020 15:02

PC Close Date & Time

28 AUG 2020 17:32

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 11:12

PC Open Date & Time

28 AUG 2020 18:27

PC Close Date & Time

29 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 00:01

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

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

30 AUG 2020 12:02

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

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

31 AUG 2020 12:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

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

01 SEP 2020 15:45

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

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

02 SEP 2020 19:49

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

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

03 SEP 2020 16:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 15:16
PC Open Date & Time	28 AUG 2020 15:02
PC Close Date & Time	28 AUG 2020 17:32

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 11:13
PC Open Date & Time	28 AUG 2020 18:27
PC Close Date & Time	29 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

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 ☒

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 00:02
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

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)

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:26
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 15:46
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

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 ☒

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:50
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 16:39
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3332001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:36

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 11:25
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332001

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3332001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

22 SEP 2020 11:40

US3332001

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:04:37

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 ☒

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 OCT 2020 12:13:54

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 OCT 2020 09:08:57

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 08:46:16

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 09:05:48
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 00:03:04
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 12:01:46

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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="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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	06 DEC 2020 23:59
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US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 138

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Patient Cloud Open Date & Time	23 DEC 2020 00:01
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Patient Cloud Close Date & Time	27 DEC 2020 23:59
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US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 152

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 11:28:55
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 JAN 2021 12:47:17
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 12:46:43

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 09:56:34

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 00:23:32
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 FEB 2021 10:00:10
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

17 FEB 2021 07:09:54

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

24 FEB 2021 15:44:22

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 08:33:17

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

10 MAR 2021 18:44:32

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 08:19:25

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 12:01:38

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 09:46:25

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 08:41:22

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 08:58:44

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 APR 2021 10:10:50
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 09:19:30

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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="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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	05 SEP 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 ☐
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 ☐

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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="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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 439

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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="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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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="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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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="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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3332001

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:08:14

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		03 MAR 2021 08:33:31

US3332001

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	VISIT4

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

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) _____

US3332001

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3332001

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 FEB 2021
Collection time (00:00-23:59)	11:35 (24 HR)
Collection date and time (derived)	10 FEB 2021 11:35

US3332001

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 22:28:55

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Date of Contact	29 SEP 2020
Time of Contact	15:30
Date and Time of Contact (derived)	29 SEP 2020 15:30
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>

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	96 %	
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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EAB) (1725)		

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	96 %
---------------	------

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

Temperature	97.5 F
-------------	--------

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

Cough	None <input 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 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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"/>

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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"/>

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 29 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	98.4 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Symptom Day

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	95 %
---------------	------

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 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 29 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Symptom Day

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	95 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	96 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (7)

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Generated On: 09 Jun 2021 17:08:14

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

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Form: Symptom Log (7)

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Generated On: 09 Jun 2021 17:08:14

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 (8)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 (8)

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

Date	08 OCT 2020
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

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

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

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

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

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Generated On: 09 Jun 2021 17:08:14

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 13:27:43

Generated On: 09 Jun 2021 17:08:14

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

Date	09 OCT 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	97.7 F
-------------	--------

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

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

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

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	96 %
---------------	------

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

Temperature	97.5 F
-------------	--------

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

Cough	None <input 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 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 (10)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 (11)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	96 %	
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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Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:27:43

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 (12)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

Date	12 OCT 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	96.1 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 (12)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 29 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 (13)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:27:43

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (14)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 (14)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 OCT 2020
------	-------------

Assessment Not Done	False
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O2 Saturation	97 %
---------------	------

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

Temperature	95.5 F
-------------	--------

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

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

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

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

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Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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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Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 (15)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 (15)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	95.3 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 (15)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 (15)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

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EAB) (1725)

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Form: Symptom Log (16)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 29 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 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 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 29 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Symptom Day

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

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 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 29 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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	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 29 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

	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 29 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Date of Visit	30 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	30 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 29 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 29 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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 30 SEP 2020

End Date 30 SEP 2020

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date _____

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	02 OCT 2020
Day 5	Yes	05 OCT 2020
Day 7	Yes	07 OCT 2020
Day 9	Yes	09 OCT 2020
Day 14	Yes	12 OCT 2020
Day 21	Yes	19 OCT 2020
Day 28	Yes	29 OCT 2020

US3332001

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	SICKD1

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:10 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 13:10
Height (<i>xxx.x</i>)	69.0 in
Weight (<i>xxx.x</i>)	145 lb
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	98 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	88 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332001

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3332001

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 13:27:44

Generated On: 09 Jun 2021 17:08:14

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 SEP 2020

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 11:45
Height (xxx.x)	70.0 in
Weight (xxx.x)	145.0 lb
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3332001

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 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 OCT 2020

US3332001

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

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

Visit date (dd MMM yyyy)	12 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3332001

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:02:40

Generated On: 09 Jun 2021 17:08:14

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 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>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Height	
Weight	
BMI (xxx.x)	

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Height	
Weight	
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)	12 JAN 2021
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 16:00
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)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Height	
Weight	
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)	12 JAN 2021
Time of assessment (00:00-23:59)	16:37 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 16:37
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3332001

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3332001

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

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) 12 JAN 2021

What was the treatment time? (00:00-23:59) 16:11 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 16:11

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

US3332001

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

15:35 (24 HR)

Collection date and time (derived)

12 JAN 2021 15:35

US3332001

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	15:32
Collection Date and Time (derived)	12 JAN 2021 15:32

US3332001

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

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)	8 FEB 2021
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 13:50
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 15:19
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3332001

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 FEB 2021

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

US3332001

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

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) 8 FEB 2021

What was the treatment time? (00:00-23:59) 14:47 (24 HR)

Treatment Date and Time (derived) 8 FEB 2021 14:47

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

US3332001

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:44

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332001

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332001

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	5 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:07 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 14:07
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332001

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 MAR 2021

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

US3332001

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 MAR 2021
Collection time (00:00-23:59)	14:24 (24 HR)
Collection date and time (derived)	5 MAR 2021 14:24

US3332001

Folder: Unscheduled (2)

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:08:14

Visit Date

Please check all assessments that apply for this visit

Physical Exam

Vital Signs

Immunogenicity Assessment

Pregnancy Test

US3332001

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 13:27:42

Generated On: 09 Jun 2021 17:08:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 23 Feb 2021 13:27:42

Generated On: 09 Jun 2021 17:08:14

AEID	USA-US202-2020-MRNA-1273-P30 1000002
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	30 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 23 Feb 2021 13:27:42

Generated On: 09 Jun 2021 17:08:14

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT'S NEPHEW IS SUSPECTED EXPOSURE
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)	

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Feb 2021 13:27:42

Generated On: 09 Jun 2021 17:08:14

AEID

Adverse event

CHEST TIGHTNESS ETIOLOGY
UNKNOWN

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)

02 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Feb 2021 13:27:42

Generated On: 09 Jun 2021 17:08:14

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

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 23 Feb 2021 13:27:42

Generated On: 09 Jun 2021 17:08:14

AEID

Adverse event

TOOTH INFECTION

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)

17 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 23 Feb 2021 13:27:42

Generated On: 09 Jun 2021 17:08:14

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	False
Concomitant Procedure	True
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)	_____

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

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

Yes ☒

No ☐

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

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication ENALAPRIL MALEATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

	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)	21 MAR 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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 00:07:42

Generated On: 09 Jun 2021 17:08:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 NOV 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication LEVOTHYROXINE SODIUM

Prophylaxis Yes ☐
No ☒

Indication ACQUIRED HYPOTHYROIDISM

Dose per administration 125

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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US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication XANAX

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 NOV 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication TRIMIX [ALPROSTADIL,
PAPAVERINE, PHENTOLAMINE]

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

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

EAB) (1725)

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US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
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 checked="" type="radio"/>
	804	<input type="radio"/>

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication DICLOFENAC SODIUM

Prophylaxis Yes ☐
No ☒

Indication ACTINIC KERATOSIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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)

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication IBUPROFEN

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 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) 29 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"/>

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 00:07:42

Generated On: 09 Jun 2021 17:08:14

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 13:27:43

Generated On: 09 Jun 2021 17:08:14

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 OCT 2020	CHEST X-RAY	Adverse Event	
17 NOV 2020	ROOT CANAL	Adverse Event	

US3332001

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:08:14

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3332001

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:08:14

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 ☐

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

SAEID	USA-US202-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

SAEID	USA-US202-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	02/OCT/2020 08:46
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

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

SAEID	USA-US202-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	14/OCT/2020 11:19
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

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

SAEID	USA-US202-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	19/OCT/2020 19:18
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

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 13:27:45

Generated On: 09 Jun 2021 17:08:14

SAEID	USA-US202-2020-MRNA-1273-P301000002
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	23/OCT/2020 21:35
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

US3332001 (Prod: Foothill Family Clinic)

US3332001

Form: Participant Creation

Generated On: 09 Jun 2021 17:08:14

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'US3332001'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 22:44:31

US3332001

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:22:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 23:39:22

US3332001

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:22:56
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 22:44:31

US3332001

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	04 Nov 2020 17:11:10
User closed query 'per source, visit performed in clinic, please verify.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:17:05
Query 'per source, visit performed in clinic, please verify.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:25:51
User entered 'Clinic (Clinic)' reason for change:	(b) (4), (b) (6)	27 Oct 2020 22:25:45
Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 23:23:37
User opened query 'per source, visit performed in clinic, please verify.' (Site from CRA).	(b) (4), (b) (6)	03 Aug 2020 23:39:22
User entered 'Home (Home)'	(b) (4), (b) (6)	

US3332001

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'SCRN'	System	03 Aug 2020 23:39:22

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:23:51
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 22:44:32

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:23:53
User entered '68'	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'YEARS'	System	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '68'	System	03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:23:54
User entered 'Male (M)'	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 26 Oct 2020 23:23:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:41
User entered 'l'	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:41
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:41
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:12:41
User entered '0'		03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:12:41
User entered '0'		03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:41
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:41
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:41
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:08:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:41
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 23:40:20

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 26 Oct 2020 23:24:09
User entered '3 Aug 2020'		03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Aug 2020'	System	03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2020'	System	03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:24:12
User entered 'Amendment 1 (1)'		03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 26 Oct 2020 23:24:16
User entered 'Yes (Y)'		03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:48
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:12:48
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:24:18
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 23:41:35

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:12:48
User entered empty.	RWS_ENDPOINT	03 Aug 2020 22:44:31
	ENDPOINT (b) (4)	

US3332001

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:08:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'I'	System	03 Aug 2020 23:41:45

US3332001

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:08:14

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:24:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 23:41:45

US3332001

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:08:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:17:57
User entered 'Yes (Y)'		03 Aug 2020 23:42:11

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:26:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Thyroid cancer, LLT: Thyroid cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:53:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:53:08
Data point term sent to Coder	System	11 Aug 2020 14:51:46
User entered 'Thyroid cancer'	(b) (4), (b) (6)	11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:26:05
User entered 'un UNK 2000'	(b) (4), (b) (6)	11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:26:08
User entered 'No (N)' reason for change: Data Entry Error		11 Aug 2020 14:53:08
User entered 'Yes (Y)'		11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:26:10
User entered 'un UNK 2000' reason for change:	(b) (4), (b) (6)	11 Aug 2020 14:53:08
Data Entry Error		
User entered empty.		11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2000'	System	11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2000'	System	11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2000'	System	11 Aug 2020 14:53:08
User entered empty.	System	11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2000'	System	11 Aug 2020 14:53:08
User entered empty.	System	11 Aug 2020 14:51:23

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:26:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:53:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:53:09
Data point term sent to Coder	System	11 Aug 2020 14:52:48
User entered 'Sleep apnea'	(b) (4), (b) (6)	11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 26 Oct 2020 23:26:36
User entered '31 Oct 2018'		11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:26:38
User entered 'Yes (Y)'		11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Oct 2018'	System	11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2018'	System	11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 14:52:26

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:26:44
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:53:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:53:12
Data point term sent to Coder	System	11 Aug 2020 16:52:06
User entered 'low testosterone'	(b) (4), (b) (6)	11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 26 Oct 2020 23:26:45
User entered '29 Nov 2017'		11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:26:47
User entered 'Yes (Y)'		11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Nov 2017'	System	11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2017'	System	11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:51:32

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:26:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:57:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:57:16
Data point term sent to Coder	System	11 Aug 2020 16:53:11
User entered 'actinic keratosis (facial and bilateral upper extremities)'	(b) (4), (b) (6)	11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:27:28
User entered 'un UNK 2000'		11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:27:30
User entered 'Yes (Y)'		11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2000'	System	11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2000'	System	11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:52:37

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:27:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:52:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:52:22
Data point term sent to Coder	System	11 Aug 2020 16:53:11
User entered 'thyroid removal'	(b) (4), (b) (6)	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:27:54
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).		24 Sep 2020 20:46:17
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'Data entry error.' (Site from DM).	Ty Henry (b) (4) (b) (4)	23 Sep 2020 19:43:52
User entered 'No (N)' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	23 Sep 2020 19:43:23
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:42:05
User entered 'Yes (Y)'		11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:27:58
User entered 'un UNK 2000' reason for change: Data Entry Error	Ty Henry (b) (4)	23 Sep 2020 19:43:23
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2000'	System	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2000'	System	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2000'	System	23 Sep 2020 19:43:23
User entered empty.	System	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2000'	System	23 Sep 2020 19:43:23
User entered empty.	System	11 Aug 2020 16:52:55

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:28:14
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Acquired hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:16
Data point term sent to Coder	System	11 Aug 2020 16:54:12
User entered 'acquired hypothyroidism'	(b) (4), (b) (6)	11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:28:16
User entered 'un UNK 2000'		11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:28:18
User entered 'Yes (Y)'		11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2000'	System	11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2000'	System	11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:53:12

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:29:14
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Alcoholism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:16
Data point term sent to Coder	System	11 Aug 2020 16:54:12
User entered 'alcoholism'	(b) (4), (b) (6)	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:29:16
User entered 'un UNK 1970'		11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User closed query 'per source, it is not ongoing condition, please verify.' (Site from CRA).	(b) (4)	28 Oct 2020 20:19:00
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:18:52
Query 'per source, it is not ongoing condition, please verify.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:25:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 22:25:12
User opened query 'per source, it is not ongoing condition, please verify.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 23:30:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User closed query 'per source, it is UN/UNK/2018, Please verify.' (Site from CRA).	(b) (4)	28 Oct 2020 20:19:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:19:10
Query 'per source, it is UN/UNK/2018, Please verify. answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:25:23
User entered 'UN UNK 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 22:25:12
User opened query 'per source, it is UN/UNK/2018, Please verify.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 23:31:38
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 1970'	System	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '1970'	System	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2018'	System	27 Oct 2020 22:25:12
User entered empty.	System	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2018'	System	27 Oct 2020 22:25:12
User entered empty.	System	11 Aug 2020 16:53:33

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:32:00
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) (b) (4)	11 Aug 2020 16:55:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:18
Data point term sent to Coder	System	11 Aug 2020 16:54:15
User entered 'insomnia'	(b) (4), (b) (6)	11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:32:01
User entered 'un UNK 2018'		11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:32:03
User entered 'Yes (Y)'		11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2018'	System	11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2018'	System	11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:53:47

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:32:08
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:18
Data point term sent to Coder	System	11 Aug 2020 16:54:15
User entered 'hypertension'	(b) (4), (b) (6)	11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:32:09
User entered 'un UNK 2018'		11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:32:11
User entered 'Yes (Y)'		11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'Jan 2018'	System	11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '2018'	System	11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:08:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered empty.	System	11 Aug 2020 16:54:04

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:32:28
User entered 'Yes (Y)'		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:13:02
User closed query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:33:34
Query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' answered with ' ' (Site from DM).		06 Nov 2020 21:13:09
DataPoint Un-verified.		06 Nov 2020 21:13:03
User entered '03 Aug 2020' reason for change: Data Entry Error		06 Nov 2020 21:13:03
User opened query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).		06 Nov 2020 18:11:04
DataPoint Verified.		26 Oct 2020 23:32:29
User entered '3 Aug 2020'		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:34:19
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 21:58:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 21:58:45
User entered '16:10' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 16:50:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:50:03
User entered '16:10' reason for change: Data Entry Error		11 Aug 2020 16:49:03
User entered '17:55'		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered '03 Aug 2020 16:10'	System	06 Nov 2020 21:13:03
User entered '3 Aug 2020 16:10'	System	26 Oct 2020 21:58:45
User entered empty.	System	22 Oct 2020 16:50:03
User entered '3 Aug 2020 16:10'	System	11 Aug 2020 16:49:03
User entered '3 Aug 2020 17:55'	System	11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:34:21
User entered '70.0' in		11 Aug 2020 14:47:00
DataPoint set to visible.	System	03 Aug 2020 23:41:45

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:35:57
User entered '145.0' lb		11 Aug 2020 14:47:00
DataPoint set to visible.	System	03 Aug 2020 23:41:45

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
Amendment Manager: User entered '20.84884'	System	16 Sep 2020 23:41:56
User entered '20.8'	System	11 Aug 2020 14:47:00
DataPoint set to visible.	System	03 Aug 2020 23:41:45

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'kg/m2'	System	11 Aug 2020 14:47:00
DataPoint set to visible.	System	03 Aug 2020 23:41:45

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:26:06
DataPoint Verified.		26 Oct 2020 23:36:09
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly' answered with 'ENTERED CORRECTLY PER GUIDELINES' (Site from DM).		26 Oct 2020 22:01:13
User entered missing code ND - Not Done; reason for change Data Entry Error		26 Oct 2020 21:58:45
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly' (Site from DM).		21 Oct 2020 12:01:43
User entered '98.2' F		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:02
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 21:58:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).		26 Oct 2020 21:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 16:50:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:50:03
User entered 'Oral (Oral)'		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:02
User entered empty.		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:02
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 21:58:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 21:58:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 16:50:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:50:03
User entered '89' reason for change: Data Entry Error		11 Aug 2020 16:49:03
User entered '75'		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'bpm'	System	26 Oct 2020 21:58:45
User entered empty.	System	22 Oct 2020 16:50:03
User entered 'bpm'	System	11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:02
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 21:58:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 21:58:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 16:50:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:50:03
User entered '16'		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'breaths/min'	System	26 Oct 2020 21:58:45
User entered empty.	System	22 Oct 2020 16:50:03
User entered 'breaths/min'	System	11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:02
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 21:58:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 21:58:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 16:50:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:50:03
User entered '130' reason for change: Data Entry Error		11 Aug 2020 16:49:03
User entered '126'		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'mmHg'	System	26 Oct 2020 21:58:45
User entered empty.	System	22 Oct 2020 16:50:03
User entered 'mmHg'	System	11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:02
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Oct 2020 21:58:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Oct 2020 21:58:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:58:45
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 16:50:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:50:03
User entered '75' reason for change: Data Entry Error		11 Aug 2020 16:49:03
User entered '80'		11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User entered 'mmHg'	System	26 Oct 2020 21:58:45
User entered empty.	System	22 Oct 2020 16:50:03
User entered 'mmHg'	System	11 Aug 2020 14:47:00

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02

US3332001

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02

US3332001

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:36:26
User entered 'Yes (Y)'	Megan Grimmatt (b) (4)	07 Aug 2020 16:26:02

US3332001

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:36:28
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).		07 Sep 2020 11:04:19
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		28 Aug 2020 20:59:18
User entered '03 Aug 2020'	Megan Grimmatt (b) (4)	07 Aug 2020 16:26:02
	(b) (4)	

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:38:57
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:38:59
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:39:01
User entered 'Yes (Y)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:39:04
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:39:05
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:39:08
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:39:09
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:39:12
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:39:13
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:39:16
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:39:18
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:39:20
User entered 'No (N)'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:21
User entered empty.		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:13:21
User entered '0'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:13:21
User entered '0'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:21
User entered '0'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:13:21
User entered '0'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:13:21
User entered '0'		04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 00:23:29

US3332001

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:08:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:45:02
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:13:21
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 00:23:29

US3332001

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:14:46
User entered 'Yes (Y)'		04 Aug 2020 00:21:11

US3332001

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Un-verified.	(b) (4)	10 Nov 2020 16:39:07
User entered '03 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 16:39:07
DataPoint Verified.		26 Oct 2020 23:14:48
User entered '3 Aug 2020'		04 Aug 2020 00:21:11

US3332001

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User closed query 'Source shows visit performed at the clinic, please verify.' (Site from CRA).	(b) (4)	28 Oct 2020 19:39:37
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:39:31
Query 'Source shows visit performed at the clinic, please verify.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:29:12
User entered 'Clinic (Clinic)' reason for change:	(b) (4), (b) (6)	27 Oct 2020 22:29:05
Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 23:17:27
User opened query 'Source shows visit performed at the clinic, please verify.' (Site from CRA).	(b) (4), (b) (6)	04 Aug 2020 00:21:11
User entered 'Home (Home)'	(b) (4), (b) (6)	

US3332001

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'VISIT1'	System	04 Aug 2020 00:21:11

US3332001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:19:44
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:04:06

US3332001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:14

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:13:33
DataPoint Un-verified.	(b) (4), (b) (6)	26 Oct 2020 23:19:48
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:19:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:51:55
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:51:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 23:04:06
User entered '184583' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 23:04:06

US3332001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:19:50
User entered '>=65 years (3)'	(b) (4), (b) (6)	
	RWS_ENDPOINT	03 Aug 2020 23:04:06
	ENDPOINT (b) (4)	

US3332001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:14

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:20:50
User entered 'No (N)'		04 Aug 2020 00:21:32

US3332001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:14

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:20:53
User entered 'No (N)'		04 Aug 2020 00:21:32

US3332001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:14

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:21:01
User entered 'No (N)'		04 Aug 2020 00:21:32

US3332001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:14

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:21:03
User entered 'No (N)'		04 Aug 2020 00:21:32

US3332001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:08:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:21:04
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 00:21:32

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User closed query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' (Site from DM).	(b) (4)	28 Oct 2020 07:15:08
Query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 22:30:04
User opened query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:28:01
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' i Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:26:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:41:14
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 21:51:30
User entered missing code ND - Not Done; reason fo change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:51:02
User entered '69.0' in reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:50:38
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' i Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:03:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:29:45
User entered '70.0' in	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:40
User entered missing code ND - Not Done; reason for change Data Entry Error		27 Oct 2020 22:29:43
User entered empty; reason for change Data Entry Error		14 Aug 2020 01:29:45
User entered '145.0' lb		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User closed query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' (Site from DM).	(b) (4)	28 Oct 2020 07:15:08
Query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 22:30:04
User opened query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:28:01
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:26:24
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 23:41:14
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 21:51:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:51:02
User entered '69.0' in reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:50:38
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:03:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:29:45
User entered '70.0' in	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:40
User entered missing code ND - Not Done; reason for change Data Entry Error		27 Oct 2020 22:29:43
User entered empty; reason for change Data Entry Error		14 Aug 2020 01:29:45
User entered '145.0' lb		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User accepted default value 'Pre-Dose (PREDOSE)'		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:42:18
User entered 'Yes (Y)'		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:42:20
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:44:48
User entered '16:10'		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '3 Aug 2020 16:10'	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:43:32
User entered '98.2' F	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:43:34
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:40
User entered empty.		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:43:17
User entered '89'		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'bpm'	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:43:16
User entered '16'		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'breaths/min'	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:42:51
User entered '130'		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	26 Oct 2020 23:42:52
User entered '75'	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
User closed query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 28 Oct 2020 07:15:08
Query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' answered with 'UPDATED' (Site from DM).		27 Oct 2020 22:30:04
User opened query 'Per CDM Requery-Thank you for the response,However,Not done is not yet updated in the 'Weight' field.Kindly consider to verify and update data appropriately.' (Site from DM).		27 Oct 2020 05:28:01
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).		27 Oct 2020 05:26:24
DataPoint Verified.		26 Oct 2020 23:41:14
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'UPDATED' (Site from DM).		26 Oct 2020 21:51:30
User entered missing code ND - Not Done; reason for change Data Entry Error		26 Oct 2020 21:51:02
User entered '69.0' in reason for change: Data Entry Error		26 Oct 2020 21:50:38
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM).		21 Oct 2020 12:03:32
User entered empty; reason for change Data Entry Error		14 Aug 2020 01:29:45
User entered '70.0' in		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:13:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 22:29:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:29:45
User entered '145.0' lb	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User accepted default value 'Post-Dose (POSTDOSE)'		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:45:15
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 00:22:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 00:22:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Aug 2020 00:22:59
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 23:51:00
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:45:16
User entered '3 Aug 2020' reason for change: Data Entry Error		04 Aug 2020 00:22:59
User entered empty.		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:45:20
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 10:19:19
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Data entered is correct - completed per protocol. ' (Site from System).	Megan Grimmatt (b) (4) (b) (4)	07 Aug 2020 16:34:21
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 00:22:59
User entered '17:55' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Aug 2020 00:22:59
User entered empty.		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '3 Aug 2020 17:55'	System	04 Aug 2020 00:22:59
User entered empty.	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:48:01
User entered '98.0' F reason for change: Data Entry Error		04 Aug 2020 00:22:59
User entered empty.		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:48:02
User entered 'Oral (Oral)' reason for change: Data Entry Error		04 Aug 2020 00:22:59
User entered empty.		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:40
User entered empty.		03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:48:05
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 16:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 16:34:05
User entered '75' reason for change: Data Entry Error	Megan Grimmatt (b) (4) (b) (4)	07 Aug 2020 16:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Aug 2020 00:22:59
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'bpm'	System	07 Aug 2020 16:34:05
User entered empty.	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:48:03
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 16:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 16:34:05
User entered '16' reason for change: Data Entry Error	Megan Grimmatt (b) (4) (b) (4)	07 Aug 2020 16:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Aug 2020 00:22:59
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'breaths/min'	System	07 Aug 2020 16:34:05
User entered empty.	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:47:45
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 16:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 16:34:05
User entered '126' reason for change: Data Entry Error	Megan Grimmatt (b) (4) (b) (4)	07 Aug 2020 16:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Aug 2020 00:22:59
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	07 Aug 2020 16:34:05
User entered empty.	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 23:47:46
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Aug 2020 16:34:05
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Aug 2020 16:34:05
User entered '80' reason for change: Data Entry Error	Megan Grimmatt (b) (4) (b) (4)	07 Aug 2020 16:34:05
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Aug 2020 00:22:59
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	07 Aug 2020 16:34:05
User entered empty.	System	03 Aug 2020 23:51:00

US3332001

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	04 Nov 2020 17:26:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:30:04
User entered 'Yes (Y)'		04 Aug 2020 00:21:41

US3332001

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:13:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 01:30:04
User entered '3 Aug 2020'		04 Aug 2020 00:21:41

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	27 Oct 2020 03:47:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:13:52
User entered empty.		03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:13:52
User entered empty.		03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	10 Nov 2020 03:13:52
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:33:08
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' answered with '.' (Site from DM).		06 Nov 2020 21:13:28
DataPoint Un-verified.		06 Nov 2020 21:13:23
User entered '03 Aug 2020' reason for change: Data Entry Error		06 Nov 2020 21:13:23
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' (Site from DM).		06 Nov 2020 17:06:05
DataPoint Verified.		27 Oct 2020 03:47:44
User entered '3 Aug 2020'		03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:47:41
User entered '17:22'		03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '03 Aug 2020 17:22'	System	06 Nov 2020 21:13:23
User entered '3 Aug 2020 17:22'	System	03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 03:47:52
User entered 'Left Arm (LEFT ARM)'		03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
DataPoint Verified.		27 Oct 2020 03:47:53
User entered 'ONCE'	System	03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 23:48:00

US3332001

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:41:21
User entered 'Yes (Y)'		03 Aug 2020 23:51:17

US3332001

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 28 Oct 2020 19:41:23
User entered '3 Aug 2020'		03 Aug 2020 23:51:17

US3332001

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	28 Oct 2020 19:41:24
User entered '16:30'	(b) (4), (b) (6)	03 Aug 2020 23:51:17

US3332001

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '3 Aug 2020 16:30'	System	03 Aug 2020 23:51:17

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	28 Oct 2020 19:41:36
User entered '3 Aug 2020'	(b) (4), (b) (6)	04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:41:46
User entered 'Yes (Y)'		04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	28 Oct 2020 19:41:47
User entered '16:45'	(b) (4), (b) (6)	04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:14

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '3 Aug 2020 16:45'	System	04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:26:34
User entered 'No (N)'		04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:14:03
User entered empty.		04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered empty.	System	04 Aug 2020 00:20:48

US3332001

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:42:35
User entered 'Yes (Y)'		04 Aug 2020 00:20:52

US3332001

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	04 Aug 2020 00:20:52

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:55:27', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0864d82d-8359-48aa-ac43-8fe57fe6c9bf' User entered 'Yes (Y)'	System	03 Aug 2020 23:56:07
	System	03 Aug 2020 23:56:07

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:55:49', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0864d82d-8359-48aa-ac43-8fe57fe6c9bf' User entered '98.2'	System	03 Aug 2020 23:56:07
	System	03 Aug 2020 23:56:07

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:55:56', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0864d82d-8359-48aa-ac43-8fe57fe6c9bf' User entered 'No (N)'	System	03 Aug 2020 23:56:07
	System	03 Aug 2020 23:56:07

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:56:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0864d82d-8359-48aa-ac43-8fe57fe6c9bf' User entered '03 Aug 2020 17:56'	System	03 Aug 2020 23:56:07
	System	03 Aug 2020 23:56:07

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 17:42'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 20:12'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:13:11', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2906a4cd-226d-444e-af39-ba817aaf0180' User entered 'Yes (Y)'	System	04 Aug 2020 04:13:43
	System	04 Aug 2020 04:13:43

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:13:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2906a4cd-226d-444e-af39-ba817aaf0180' User entered '97.4'	System	04 Aug 2020 04:13:43
	System	04 Aug 2020 04:13:43

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:13:29', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2906a4cd-226d-444e-af39-ba817aaf0180'	System	04 Aug 2020 04:13:43
User entered 'No (N)'	System	04 Aug 2020 04:13:43

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:13:42', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2906a4cd-226d-444e-af39-ba817aaf0180' User entered '03 Aug 2020 22:13'	System	04 Aug 2020 04:13:43
	System	04 Aug 2020 04:13:43

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 21:07'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 2'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:06:29', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2f521080-67af-4516-96ba-4b6a42acc999'	System	04 Aug 2020 18:06:49
User entered 'Yes (Y)'	System	04 Aug 2020 18:06:49

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:06:36', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2f521080-67af-4516-96ba-4b6a42acc999' User entered '96.4'	System	04 Aug 2020 18:06:49
	System	04 Aug 2020 18:06:49

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:06:41', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2f521080-67af-4516-96ba-4b6a42acc999'	System	04 Aug 2020 18:06:49
User entered 'No (N)'	System	04 Aug 2020 18:06:49

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:06:48', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2f521080-67af-4516-96ba-4b6a42acc999'	System	04 Aug 2020 18:06:49
User entered '04 Aug 2020 12:06'	System	04 Aug 2020 18:06:49

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 3'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:01:57', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '60225ded-186e-4cae-8709-b8572cd3ca1a' User entered 'Yes (Y)'	System	06 Aug 2020 12:02:25
	System	06 Aug 2020 12:02:25

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:02:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '60225ded-186e-4cae-8709-b8572cd3ca1a' User entered '97.4'	System	06 Aug 2020 12:02:25
	System	06 Aug 2020 12:02:25

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:02:16', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '60225ded-186e-4cae-8709-b8572cd3ca1a' User entered 'No (N)'	System	06 Aug 2020 12:02:25
	System	06 Aug 2020 12:02:25

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:02:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '60225ded-186e-4cae-8709-b8572cd3ca1a' User entered '06 Aug 2020 06:02'	System	06 Aug 2020 12:02:25
	System	06 Aug 2020 12:02:25

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 4'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:25:06', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b1863a1-c243-4b07-aa46-4e155ee6c00c' User entered 'Yes (Y)'	System	06 Aug 2020 18:25:54
	System	06 Aug 2020 18:25:54

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:25:40', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b1863a1-c243-4b07-aa46-4e155ee6c00c' User entered '96.3'	System	06 Aug 2020 18:25:54
	System	06 Aug 2020 18:25:54

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:25:44', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b1863a1-c243-4b07-aa46-4e155ee6c00c' User entered 'No (N)'	System	06 Aug 2020 18:25:54
	System	06 Aug 2020 18:25:54

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:25:50', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b1863a1-c243-4b07-aa46-4e155ee6c00c' User entered '06 Aug 2020 12:25'	System	06 Aug 2020 18:25:54
	System	06 Aug 2020 18:25:54

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 5'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:43:38', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '15851c35-c81b-4725-a84d-5bce6066cd2a' User entered 'Yes (Y)'	System	07 Aug 2020 18:44:04
	System	07 Aug 2020 18:44:04

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:43:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '15851c35-c81b-4725-a84d-5bce6066cd2a' User entered '97.6'	System	07 Aug 2020 18:44:04
	System	07 Aug 2020 18:44:04

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:43:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '15851c35-c81b-4725-a84d-5bce6066cd2a' User entered 'No (N)'	System	07 Aug 2020 18:44:04
	System	07 Aug 2020 18:44:04

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:01', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '15851c35-c81b-4725-a84d-5bce6066cd2a' User entered '07 Aug 2020 12:44'	System	07 Aug 2020 18:44:04
	System	07 Aug 2020 18:44:04

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 6'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:16:36', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'f1ba1f83-d6db-4f8d-b27e-91a8d0f72118'	System	08 Aug 2020 18:17:29
User entered 'Yes (Y)'	System	08 Aug 2020 18:17:29

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:17:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'f1ba1f83-d6db-4f8d-b27e-91a8d0f72118' User entered '97.8'	System	08 Aug 2020 18:17:29
	System	08 Aug 2020 18:17:29

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:17:20', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'f1ba1f83-d6db-4f8d-b27e-91a8d0f72118'	System	08 Aug 2020 18:17:29
User entered 'No (N)'	System	08 Aug 2020 18:17:29

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:17:28', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'f1ba1f83-d6db-4f8d-b27e-91a8d0f72118' User entered '08 Aug 2020 12:17'	System	08 Aug 2020 18:17:29
	System	08 Aug 2020 18:17:29

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 7'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:24:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e3492972-4f2b-4e3f-8549-50f69d0244a1' User entered 'Yes (Y)'	System	09 Aug 2020 18:24:39
	System	09 Aug 2020 18:24:39

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:24:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e3492972-4f2b-4e3f-8549-50f69d0244a1' User entered '97.4'	System	09 Aug 2020 18:24:39
	System	09 Aug 2020 18:24:39

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:24:28', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e3492972-4f2b-4e3f-8549-50f69d0244a1' User entered 'No (N)'	System	09 Aug 2020 18:24:39
	System	09 Aug 2020 18:24:39

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:24:34', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e3492972-4f2b-4e3f-8549-50f69d0244a1' User entered '09 Aug 2020 12:24'	System	09 Aug 2020 18:24:39
	System	09 Aug 2020 18:24:39

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:56:25', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cc178877-3dde-4809-b97d-1f7976c94d79' User entered 'None (1)'	System	03 Aug 2020 23:57:08
	System	03 Aug 2020 23:57:08

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:56:33', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cc178877-3dde-4809-b97d-1f7976c94d79' User entered 'No (N)'	System	03 Aug 2020 23:57:08
	System	03 Aug 2020 23:57:08

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:56:40', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cc178877-3dde-4809-b97d-1f7976c94d79' User entered 'No (N)'	System	03 Aug 2020 23:57:08
	System	03 Aug 2020 23:57:08

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:56:57', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cc178877-3dde-4809-b97d-1f7976c94d79'	System	03 Aug 2020 23:57:08
User entered 'None (1)'	System	03 Aug 2020 23:57:08

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:04', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cc178877-3dde-4809-b97d-1f7976c94d79' User entered '03 Aug 2020 17:57'	System	03 Aug 2020 23:57:08
	System	03 Aug 2020 23:57:08

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 17:42'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 20:12'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:14:04', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '42087dfb-eb6f-40f2-9838-64f3a650898c' User entered 'None (1)'	System	04 Aug 2020 04:15:00
	System	04 Aug 2020 04:15:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:14:26', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '42087dfb-eb6f-40f2-9838-64f3a650898c'	System	04 Aug 2020 04:15:00
User entered 'No (N)'	System	04 Aug 2020 04:15:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:14:31', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '42087dfb-eb6f-40f2-9838-64f3a650898c'	System	04 Aug 2020 04:15:00
User entered 'No (N)'	System	04 Aug 2020 04:15:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:14:45', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '42087dfb-eb6f-40f2-9838-64f3a650898c' User entered 'None (1)'	System	04 Aug 2020 04:15:00
	System	04 Aug 2020 04:15:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:14:58', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '42087dfb-eb6f-40f2-9838-64f3a650898c' User entered '03 Aug 2020 22:14'	System	04 Aug 2020 04:15:00
	System	04 Aug 2020 04:15:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 21:07'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 2'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:06:59', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1fdd9b-f259-483d-9ccb-18dc5c96f8b8'	System	04 Aug 2020 18:07:34
User entered 'None (1)'	System	04 Aug 2020 18:07:34

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:05', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1fdd9b-f259-483d-9ccb-18dc5c96f8b8'	System	04 Aug 2020 18:07:34
User entered 'No (N)'	System	04 Aug 2020 18:07:34

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:10', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1fdd9b-f259-483d-9ccb-18dc5c96f8b8'	System	04 Aug 2020 18:07:34
User entered 'No (N)'	System	04 Aug 2020 18:07:34

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:19', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1fdd9b-f259-483d-9ccb-18dc5c96f8b8'	System	04 Aug 2020 18:07:34
User entered 'None (1)'	System	04 Aug 2020 18:07:34

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1fdd9b-f259-483d-9ccb-18dc5c96f8b8'	System	04 Aug 2020 18:07:34
User entered '04 Aug 2020 12:07'	System	04 Aug 2020 18:07:34

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 3'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:02:30', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7483288d-b0ce-4c55-ad76-cabf7621aa94'	System	06 Aug 2020 12:03:10
User entered 'None (1)'	System	06 Aug 2020 12:03:10

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:02:34', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7483288d-b0ce-4c55-ad76-cabf7621aa94'	System	06 Aug 2020 12:03:10
User entered 'No (N)'	System	06 Aug 2020 12:03:10

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:02:40', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7483288d-b0ce-4c55-ad76-cabf7621aa94' User entered 'No (N)'	System	06 Aug 2020 12:03:10
	System	06 Aug 2020 12:03:10

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:02:44', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7483288d-b0ce-4c55-ad76-cabf7621aa94'	System	06 Aug 2020 12:03:10
User entered 'None (1)'	System	06 Aug 2020 12:03:10

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:08', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7483288d-b0ce-4c55-ad76-cabf7621aa94' User entered '06 Aug 2020 06:03'	System	06 Aug 2020 12:03:10
	System	06 Aug 2020 12:03:10

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 4'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:25:56', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cd1f56d5-dbbb-4cb4-a46c-e2349acc0954' User entered 'None (1)'	System	06 Aug 2020 18:26:17
	System	06 Aug 2020 18:26:17

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cd1f56d5-dbbb-4cb4-a46c-e2349acc0954' User entered 'No (N)'	System	06 Aug 2020 18:26:17
	System	06 Aug 2020 18:26:17

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:04', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cd1f56d5-dbbb-4cb4-a46c-e2349acc0954' User entered 'No (N)'	System	06 Aug 2020 18:26:17
	System	06 Aug 2020 18:26:17

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:09', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cd1f56d5-dbbb-4cb4-a46c-e2349acc0954' User entered 'None (1)'	System	06 Aug 2020 18:26:17
	System	06 Aug 2020 18:26:17

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:14', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cd1f56d5-dbbb-4cb4-a46c-e2349acc0954' User entered '06 Aug 2020 12:26'	System	06 Aug 2020 18:26:17
	System	06 Aug 2020 18:26:17

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 5'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:07', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b9055ada-bb7d-46d2-95c8-c6218aea2304' User entered 'None (1)'	System	07 Aug 2020 18:44:32
	System	07 Aug 2020 18:44:32

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:11', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b9055ada-bb7d-46d2-95c8-c6218aea2304' User entered 'No (N)'	System	07 Aug 2020 18:44:32
	System	07 Aug 2020 18:44:32

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:14', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b9055ada-bb7d-46d2-95c8-c6218aea2304' User entered 'No (N)'	System	07 Aug 2020 18:44:32
	System	07 Aug 2020 18:44:32

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:22', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b9055ada-bb7d-46d2-95c8-c6218aea2304' User entered 'None (1)'	System	07 Aug 2020 18:44:32
	System	07 Aug 2020 18:44:32

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:30', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b9055ada-bb7d-46d2-95c8-c6218aea2304' User entered '07 Aug 2020 12:44'	System	07 Aug 2020 18:44:32
	System	07 Aug 2020 18:44:32

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 6'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:17:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a9d6e718-877e-4162-b8d8-a4d7b2d3de45'	System	08 Aug 2020 18:17:56
User entered 'None (1)'	System	08 Aug 2020 18:17:56

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:17:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a9d6e718-877e-4162-b8d8-a4d7b2d3de45'	System	08 Aug 2020 18:17:56
User entered 'No (N)'	System	08 Aug 2020 18:17:56

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:17:41', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a9d6e718-877e-4162-b8d8-a4d7b2d3de45'	System	08 Aug 2020 18:17:56
User entered 'No (N)'	System	08 Aug 2020 18:17:56

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:17:45', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a9d6e718-877e-4162-b8d8-a4d7b2d3de45'	System	08 Aug 2020 18:17:56
User entered 'None (1)'	System	08 Aug 2020 18:17:56

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:17:55', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a9d6e718-877e-4162-b8d8-a4d7b2d3de45'	System	08 Aug 2020 18:17:56
User entered '08 Aug 2020 12:17'	System	08 Aug 2020 18:17:56

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 7'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:24:39', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a60b5a1e-25f4-4076-a5e8-7a0e4bc9bd5b' User entered 'None (1)'	System	09 Aug 2020 18:25:28
	System	09 Aug 2020 18:25:28

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:24:44', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a60b5a1e-25f4-4076-a5e8-7a0e4bc9bd5b' User entered 'No (N)'	System	09 Aug 2020 18:25:28
	System	09 Aug 2020 18:25:28

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:24:58', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a60b5a1e-25f4-4076-a5e8-7a0e4bc9bd5b' User entered 'No (N)'	System	09 Aug 2020 18:25:28
	System	09 Aug 2020 18:25:28

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:25:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a60b5a1e-25f4-4076-a5e8-7a0e4bc9bd5b' User entered 'None (1)'	System	09 Aug 2020 18:25:28
	System	09 Aug 2020 18:25:28

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:25:24', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a60b5a1e-25f4-4076-a5e8-7a0e4bc9bd5b' User entered '09 Aug 2020 12:25'	System	09 Aug 2020 18:25:28
	System	09 Aug 2020 18:25:28

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:19', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'bec4abf8-fcf7-4319-b8e5-c736bfdfebdb' User entered 'None (0)'	System	03 Aug 2020 23:57:57
	System	03 Aug 2020 23:57:57

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:24', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'bec4abf8-fcf7-4319-b8e5-c736bfdfebdb' User entered 'None (0)'	System	03 Aug 2020 23:57:57
	System	03 Aug 2020 23:57:57

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:29', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'bec4abf8-fcf7-4319-b8e5-c736bfdfebdb' User entered 'None (0)'	System	03 Aug 2020 23:57:57
	System	03 Aug 2020 23:57:57

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:35', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'bec4abf8-fcf7-4319-b8e5-c736bfdfebdb' User entered 'None (0)'	System	03 Aug 2020 23:57:57
	System	03 Aug 2020 23:57:57

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:38', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'bec4abf8-fcf7-4319-b8e5-c736bfdfebdb' User entered 'None (0)'	System	03 Aug 2020 23:57:57
	System	03 Aug 2020 23:57:57

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:42', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'bec4abf8-fcf7-4319-b8e5-c736bfdfebdb' User entered 'None (0)'	System	03 Aug 2020 23:57:57
	System	03 Aug 2020 23:57:57

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:49', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'bec4abf8-fcf7-4319-b8e5-c736bfdfebdb' User entered 'No (N)'	System	03 Aug 2020 23:57:57
	System	03 Aug 2020 23:57:57

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T17:57:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'bec4abf8-fcf7-4319-b8e5-c736bfdfebdb' User entered '03 Aug 2020 17:57'	System	03 Aug 2020 23:57:57
	System	03 Aug 2020 23:57:57

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 17:42'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 20:12'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:15:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '363a5c59-ddb3-4528-8a2f-ecfa9a7795ed' User entered 'None (0)'	System	04 Aug 2020 04:16:19
	System	04 Aug 2020 04:16:19

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:15:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '363a5c59-ddb3-4528-8a2f-ecfa9a7795ed' User entered 'None (0)'	System	04 Aug 2020 04:16:19
	System	04 Aug 2020 04:16:19

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:15:38', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '363a5c59-ddb3-4528-8a2f-ecfa9a7795ed' User entered 'None (0)'	System	04 Aug 2020 04:16:19
	System	04 Aug 2020 04:16:19

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:15:44', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '363a5c59-ddb3-4528-8a2f-ecfa9a7795ed' User entered 'None (0)'	System	04 Aug 2020 04:16:19
	System	04 Aug 2020 04:16:19

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:15:48', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '363a5c59-ddb3-4528-8a2f-ecfa9a7795ed' User entered 'None (0)'	System	04 Aug 2020 04:16:19
	System	04 Aug 2020 04:16:19

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:15:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '363a5c59-ddb3-4528-8a2f-ecfa9a7795ed' User entered 'None (0)'	System	04 Aug 2020 04:16:19
	System	04 Aug 2020 04:16:19

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:16:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '363a5c59-ddb3-4528-8a2f-ecfa9a7795ed' User entered 'No (N)'	System	04 Aug 2020 04:16:19
	System	04 Aug 2020 04:16:19

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-03T22:16:17', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '363a5c59-ddb3-4528-8a2f-ecfa9a7795ed' User entered '03 Aug 2020 22:16'	System	04 Aug 2020 04:16:19
	System	04 Aug 2020 04:16:19

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Aug 2020 21:07'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 2'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:40', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5954166d-e8cc-49bf-83af-9e4e2adc3458' User entered 'None (0)'	System	04 Aug 2020 18:08:18
	System	04 Aug 2020 18:08:18

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:44', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5954166d-e8cc-49bf-83af-9e4e2adc3458' User entered 'None (0)'	System	04 Aug 2020 18:08:18
	System	04 Aug 2020 18:08:18

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:48', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5954166d-e8cc-49bf-83af-9e4e2adc3458' User entered 'None (0)'	System	04 Aug 2020 18:08:18
	System	04 Aug 2020 18:08:18

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:52', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5954166d-e8cc-49bf-83af-9e4e2adc3458' User entered 'None (0)'	System	04 Aug 2020 18:08:18
	System	04 Aug 2020 18:08:18

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:56', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5954166d-e8cc-49bf-83af-9e4e2adc3458' User entered 'None (0)'	System	04 Aug 2020 18:08:18
	System	04 Aug 2020 18:08:18

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:07:59', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5954166d-e8cc-49bf-83af-9e4e2adc3458' User entered 'None (0)'	System	04 Aug 2020 18:08:18
	System	04 Aug 2020 18:08:18

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:08:05', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5954166d-e8cc-49bf-83af-9e4e2adc3458'	System	04 Aug 2020 18:08:18
User entered 'No (N)'	System	04 Aug 2020 18:08:18

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-04T12:08:14', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5954166d-e8cc-49bf-83af-9e4e2adc3458'	System	04 Aug 2020 18:08:18
User entered '04 Aug 2020 12:08'	System	04 Aug 2020 18:08:18

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 3'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:15', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0f24997f-1305-415b-823f-99815361a90a' User entered 'None (0)'	System	06 Aug 2020 12:04:00
	System	06 Aug 2020 12:04:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:18', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0f24997f-1305-415b-823f-99815361a90a' User entered 'None (0)'	System	06 Aug 2020 12:04:00
	System	06 Aug 2020 12:04:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0f24997f-1305-415b-823f-99815361a90a' User entered 'None (0)'	System	06 Aug 2020 12:04:00
	System	06 Aug 2020 12:04:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:27', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0f24997f-1305-415b-823f-99815361a90a' User entered 'None (0)'	System	06 Aug 2020 12:04:00
	System	06 Aug 2020 12:04:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:31', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0f24997f-1305-415b-823f-99815361a90a' User entered 'None (0)'	System	06 Aug 2020 12:04:00
	System	06 Aug 2020 12:04:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:34', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0f24997f-1305-415b-823f-99815361a90a' User entered 'None (0)'	System	06 Aug 2020 12:04:00
	System	06 Aug 2020 12:04:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:46', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0f24997f-1305-415b-823f-99815361a90a' User entered 'No (N)'	System	06 Aug 2020 12:04:00
	System	06 Aug 2020 12:04:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T06:03:59', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0f24997f-1305-415b-823f-99815361a90a' User entered '06 Aug 2020 06:03'	System	06 Aug 2020 12:04:00
	System	06 Aug 2020 12:04:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 4'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:24', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '13f9e2a2-293b-48be-a36b-ffa50ec2a90e' User entered 'None (0)'	System	06 Aug 2020 18:27:01
	System	06 Aug 2020 18:27:01

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:27', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '13f9e2a2-293b-48be-a36b-ffa50ec2a90e' User entered 'None (0)'	System	06 Aug 2020 18:27:01
	System	06 Aug 2020 18:27:01

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:30', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '13f9e2a2-293b-48be-a36b-ffa50ec2a90e' User entered 'None (0)'	System	06 Aug 2020 18:27:01
	System	06 Aug 2020 18:27:01

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:35', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '13f9e2a2-293b-48be-a36b-ffa50ec2a90e' User entered 'None (0)'	System	06 Aug 2020 18:27:01
	System	06 Aug 2020 18:27:01

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:38', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '13f9e2a2-293b-48be-a36b-ffa50ec2a90e' User entered 'None (0)'	System	06 Aug 2020 18:27:01
	System	06 Aug 2020 18:27:01

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:42', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '13f9e2a2-293b-48be-a36b-ffa50ec2a90e' User entered 'None (0)'	System	06 Aug 2020 18:27:01
	System	06 Aug 2020 18:27:01

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:51', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '13f9e2a2-293b-48be-a36b-ffa50ec2a90e'	System	06 Aug 2020 18:27:01
User entered 'No (N)'	System	06 Aug 2020 18:27:01

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-06T12:26:59', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '13f9e2a2-293b-48be-a36b-ffa50ec2a90e' User entered '06 Aug 2020 12:26'	System	06 Aug 2020 18:27:01
	System	06 Aug 2020 18:27:01

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 5'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:39', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ecd79a65-5919-487b-963c-9a193e51dc81' User entered 'None (0)'	System	07 Aug 2020 18:45:16
	System	07 Aug 2020 18:45:16

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:42', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ecd79a65-5919-487b-963c-9a193e51dc81' User entered 'None (0)'	System	07 Aug 2020 18:45:16
	System	07 Aug 2020 18:45:16

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:46', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ecd79a65-5919-487b-963c-9a193e51dc81' User entered 'None (0)'	System	07 Aug 2020 18:45:16
	System	07 Aug 2020 18:45:16

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:49', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ecd79a65-5919-487b-963c-9a193e51dc81' User entered 'None (0)'	System	07 Aug 2020 18:45:16
	System	07 Aug 2020 18:45:16

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ecd79a65-5919-487b-963c-9a193e51dc81' User entered 'None (0)'	System	07 Aug 2020 18:45:16
	System	07 Aug 2020 18:45:16

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:44:56', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ecd79a65-5919-487b-963c-9a193e51dc81' User entered 'None (0)'	System	07 Aug 2020 18:45:16
	System	07 Aug 2020 18:45:16

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:45:06', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ecd79a65-5919-487b-963c-9a193e51dc81'	System	07 Aug 2020 18:45:16
User entered 'No (N)'	System	07 Aug 2020 18:45:16

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-07T12:45:13', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ecd79a65-5919-487b-963c-9a193e51dc81'	System	07 Aug 2020 18:45:16
User entered '07 Aug 2020 12:45'	System	07 Aug 2020 18:45:16

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 6'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:18:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e339a4f4-3d8a-4a60-be7d-4b54a89583ed' User entered 'None (0)'	System	08 Aug 2020 18:18:51
	System	08 Aug 2020 18:18:51

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:18:06', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e339a4f4-3d8a-4a60-be7d-4b54a89583ed' User entered 'None (0)'	System	08 Aug 2020 18:18:51
	System	08 Aug 2020 18:18:51

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:18:17', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e339a4f4-3d8a-4a60-be7d-4b54a89583ed' User entered 'None (0)'	System	08 Aug 2020 18:18:51
	System	08 Aug 2020 18:18:51

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:18:24', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e339a4f4-3d8a-4a60-be7d-4b54a89583ed' User entered 'None (0)'	System	08 Aug 2020 18:18:51
	System	08 Aug 2020 18:18:51

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:18:28', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e339a4f4-3d8a-4a60-be7d-4b54a89583ed' User entered 'None (0)'	System	08 Aug 2020 18:18:51
	System	08 Aug 2020 18:18:51

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:18:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e339a4f4-3d8a-4a60-be7d-4b54a89583ed' User entered 'None (0)'	System	08 Aug 2020 18:18:51
	System	08 Aug 2020 18:18:51

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:18:38', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e339a4f4-3d8a-4a60-be7d-4b54a89583ed' User entered 'No (N)'	System	08 Aug 2020 18:18:51
	System	08 Aug 2020 18:18:51

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-08T12:18:48', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e339a4f4-3d8a-4a60-be7d-4b54a89583ed' User entered '08 Aug 2020 12:18'	System	08 Aug 2020 18:18:51
	System	08 Aug 2020 18:18:51

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 7'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:25:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c560d819-f5ff-4a82-b4d0-4d86bbf2190c' User entered 'None (0)'	System	09 Aug 2020 18:26:32
	System	09 Aug 2020 18:26:32

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:25:43', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c560d819-f5ff-4a82-b4d0-4d86bbf2190c' User entered 'None (0)'	System	09 Aug 2020 18:26:32
	System	09 Aug 2020 18:26:32

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:25:49', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c560d819-f5ff-4a82-b4d0-4d86bbf2190c' User entered 'None (0)'	System	09 Aug 2020 18:26:32
	System	09 Aug 2020 18:26:32

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:25:56', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c560d819-f5ff-4a82-b4d0-4d86bbf2190c' User entered 'None (0)'	System	09 Aug 2020 18:26:32
	System	09 Aug 2020 18:26:32

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:26:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c560d819-f5ff-4a82-b4d0-4d86bbf2190c' User entered 'None (0)'	System	09 Aug 2020 18:26:32
	System	09 Aug 2020 18:26:32

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:26:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c560d819-f5ff-4a82-b4d0-4d86bbf2190c' User entered 'None (0)'	System	09 Aug 2020 18:26:32
	System	09 Aug 2020 18:26:32

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:26:13', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c560d819-f5ff-4a82-b4d0-4d86bbf2190c'	System	09 Aug 2020 18:26:32
User entered 'No (N)'	System	09 Aug 2020 18:26:32

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-09T12:26:31', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c560d819-f5ff-4a82-b4d0-4d86bbf2190c' User entered '09 Aug 2020 12:26'	System	09 Aug 2020 18:26:32
	System	09 Aug 2020 18:26:32

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 23:48:00

US3332001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 04:51:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 01:46:40

US3332001

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 04:51:23
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 01:46:40

US3332001

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	27 Oct 2020 04:51:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Aug 2020 01:46:40

US3332001

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:14:14
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:46:40

US3332001

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 04:51:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 01:46:45

US3332001

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	14 Aug 2020 01:46:45

US3332001

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 04:44:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:06:02

US3332001

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 04:45:01
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:06:02

US3332001

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 04:45:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Aug 2020 17:06:02

US3332001

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:14:23
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:06:02

US3332001

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	27 Oct 2020 04:45:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:06:06

US3332001

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	18 Aug 2020 17:06:06

US3332001

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	27 Oct 2020 04:34:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:58:47

US3332001

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 04:34:40
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Aug 2020 20:59:01
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	28 Aug 2020 20:59:01
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 20:59:01
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Aug 2020 20:58:47
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:58:47

US3332001

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 04:34:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 20:58:47

US3332001

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:14:34
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:58:47

US3332001

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 04:34:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:59:07

US3332001

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	28 Aug 2020 20:59:07

US3332001

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:59:18

US3332001

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:56:27
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).		31 Aug 2020 20:53:25
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'correct as entered ' (Site from System).		28 Aug 2020 21:00:46
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	28 Aug 2020 20:59:18
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:59:18

US3332001

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:56:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Aug 2020 20:59:18

US3332001

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'VISIT2'	System	28 Aug 2020 20:59:18

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User accepted default value 'Pre-Dose (PREDOSE)'		28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:57:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:57:10
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	04 Nov 2020 15:57:11
User entered '13:50'	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '28 Aug 2020 13:50'	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '98.2' F	(b) (4), (b) (6)	04 Nov 2020 15:57:13
		28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:57:14
User entered 'Oral (Oral)'		28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:14:46
User entered empty.		28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:57:33
User entered '81'		28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'bpm'	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:57:39
User closed query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	08 Sep 2020 21:30:49
Query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	08 Sep 2020 21:30:49
User entered '18' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	08 Sep 2020 21:30:49
User opened query 'Respiratory rate reported is out of range > 25 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Aug 2020 21:01:27
User entered '98'	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'breaths/min'	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:57:42
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	08 Sep 2020 21:30:49
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	08 Sep 2020 21:30:49
User entered '98' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	08 Sep 2020 21:30:49
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Aug 2020 21:01:27
User entered '65'	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:57:43
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 21:30:49
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 21:30:49
User entered '65' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	08 Sep 2020 21:30:49
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 21:01:27
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	08 Sep 2020 21:30:49
User entered empty.	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User accepted default value 'Post-Dose (POSTDOSE)'		28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:58:46
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 21:30:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 21:30:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	08 Sep 2020 21:30:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 21:01:27
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:58:42
User entered '28 Aug 2020' reason for change: Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 21:30:49
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:58:41
User closed query 'Per CDM: The treatment time on Exposure CRF is recorded as 14:42 and Vital Signs Post-Dose time is not recorded. Per protocol the post-dose vital signs are to be collected at least 30 minutes after dosing. Please reconcile' (Site from DM).		10 Sep 2020 18:57:17
Query 'Per CDM: The treatment time on Exposure CRF is recorded as 14:42 and Vital Signs Post-Dose time is not recorded. Per protocol the post-dose vital signs are to be collected at least 30 minutes after dosing. Please reconcile' answered with 'Updated' (Site from DM).	Ty Henry (b) (4) (b) (4)	08 Sep 2020 21:31:14
User entered '15:20' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	08 Sep 2020 21:30:49
User opened query 'Per CDM: The treatment time on Exposure CRF is recorded as 14:42 and Vital Signs Post-Dose time is not recorded. Per protocol the post-dose vital signs are to be collected at least 30 minutes after dosing. Please reconcile' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 19:39:14
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '28 Aug 2020 15:20'	System	08 Sep 2020 21:30:49
User entered empty.	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:58:36
User entered '97.9' F reason for change: Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 21:30:49
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:58:34
User entered 'Oral (Oral)' reason for change: Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 21:30:49
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:14:46
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:58:32
User entered '70' reason for change: Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 21:30:49
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'bpm'	System	08 Sep 2020 21:30:49
User entered empty.	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:58:31
User entered '16' reason for change: Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 21:30:49
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'breaths/min'	System	08 Sep 2020 21:30:49
User entered empty.	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:58:29
User entered '116' reason for change: Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 21:30:49
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	08 Sep 2020 21:30:49
User entered empty.	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:58:27
User entered '67' reason for change: Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 21:30:49
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	08 Sep 2020 21:30:49
User entered empty.	System	28 Aug 2020 21:01:27

US3332001

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	04 Nov 2020 15:59:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:01:37

US3332001

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:59:32
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:01:37

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	04 Nov 2020 16:00:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:14:55
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:14:55
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:00:45
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	04 Nov 2020 16:00:48
User entered '14:42'	(b) (4), (b) (6)	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '28 Aug 2020 14:42'	System	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:00:52
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:00:54
User entered 'ONCE'	System	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 21:03:22

US3332001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:01:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:04:13

US3332001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:01:13
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:04:13

US3332001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	04 Nov 2020 16:01:15
User entered '14:14'	(b) (4), (b) (6)	28 Aug 2020 21:04:13

US3332001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '28 Aug 2020 14:14'	System	28 Aug 2020 21:04:13

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:08:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:01:30
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:01:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:01:38
User entered '14:10'	(b) (4), (b) (6)	28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '28 Aug 2020 14:10'	System	28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:01:43
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:15:07
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered empty.	System	28 Aug 2020 21:04:34

US3332001

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:01:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:04:47

US3332001

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	28 Aug 2020 21:04:47

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:15:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '72b2357a-e48c-4022-9ad0-dd95831aadab' User entered 'Yes (Y)'	System	28 Aug 2020 21:15:27
	System	28 Aug 2020 21:15:27

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:15:10', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '72b2357a-e48c-4022-9ad0-dd95831aadab' User entered '97.9'	System	28 Aug 2020 21:15:27
	System	28 Aug 2020 21:15:27

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:15:17', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '72b2357a-e48c-4022-9ad0-dd95831aadab' User entered 'No (N)'	System	28 Aug 2020 21:15:27
	System	28 Aug 2020 21:15:27

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:15:25', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '72b2357a-e48c-4022-9ad0-dd95831aadab' User entered '28 Aug 2020 15:15'	System	28 Aug 2020 21:15:27
	System	28 Aug 2020 21:15:27

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 15:02'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 17:32'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:11:44', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4e51f9e3-2bbd-4eb5-b522-38e25cb792bd' User entered 'Yes (Y)'	System	29 Aug 2020 17:12:03
	System	29 Aug 2020 17:12:03

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:11:52', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4e51f9e3-2bbd-4eb5-b522-38e25cb792bd' User entered '96.3'	System	29 Aug 2020 17:12:03
	System	29 Aug 2020 17:12:03

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:11:56', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4e51f9e3-2bbd-4eb5-b522-38e25cb792bd' User entered 'No (N)'	System	29 Aug 2020 17:12:03
	System	29 Aug 2020 17:12:03

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:01', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4e51f9e3-2bbd-4eb5-b522-38e25cb792bd' User entered '29 Aug 2020 11:12'	System	29 Aug 2020 17:12:03
	System	29 Aug 2020 17:12:03

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 18:27'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 2'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:00:25', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9b0b9486-37c9-4e91-b398-aa064c5a6fd9' User entered 'Yes (Y)'	System	30 Aug 2020 06:01:12
	System	30 Aug 2020 06:01:12

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:01', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9b0b9486-37c9-4e91-b398-aa064c5a6fd9' User entered '96.8'	System	30 Aug 2020 06:01:12
	System	30 Aug 2020 06:01:12

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:05', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9b0b9486-37c9-4e91-b398-aa064c5a6fd9' User entered 'No (N)'	System	30 Aug 2020 06:01:12
	System	30 Aug 2020 06:01:12

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:09', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9b0b9486-37c9-4e91-b398-aa064c5a6fd9' User entered '30 Aug 2020 00:01'	System	30 Aug 2020 06:01:12
	System	30 Aug 2020 06:01:12

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 3'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:01:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '38a492a9-931b-4812-ba7f-ff5ff8bcd3a5' User entered 'Yes (Y)'	System	30 Aug 2020 18:01:45
	System	30 Aug 2020 18:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:01:30', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '38a492a9-931b-4812-ba7f-ff5ff8bcd3a5' User entered '96.3'	System	30 Aug 2020 18:01:45
	System	30 Aug 2020 18:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:01:38', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '38a492a9-931b-4812-ba7f-ff5ff8bcd3a5'	System	30 Aug 2020 18:01:45
User entered 'No (N)'	System	30 Aug 2020 18:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:01:43', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '38a492a9-931b-4812-ba7f-ff5ff8bcd3a5' User entered '30 Aug 2020 12:01'	System	30 Aug 2020 18:01:45
	System	30 Aug 2020 18:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 4'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:21:58', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'f9ca1ce1-cf93-4fee-8faf-b782f048b95e'	System	31 Aug 2020 18:25:29
User entered 'Yes (Y)'	System	31 Aug 2020 18:25:29

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:13', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'f9ca1ce1-cf93-4fee-8faf-b782f048b95e' User entered '97.1'	System	31 Aug 2020 18:25:29
	System	31 Aug 2020 18:25:29

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:21', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'f9ca1ce1-cf93-4fee-8faf-b782f048b95e'	System	31 Aug 2020 18:25:29
User entered 'No (N)'	System	31 Aug 2020 18:25:29

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:25', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'f9ca1ce1-cf93-4fee-8faf-b782f048b95e'	System	31 Aug 2020 18:25:29
User entered '31 Aug 2020 12:25'	System	31 Aug 2020 18:25:29

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 5'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:44:10', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b315c260-902e-4934-b14d-74eec081acd3' User entered 'Yes (Y)'	System	01 Sep 2020 21:44:39
	System	01 Sep 2020 21:44:39

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:44:26', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b315c260-902e-4934-b14d-74eec081acd3' User entered '97.5'	System	01 Sep 2020 21:44:39
	System	01 Sep 2020 21:44:39

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:44:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b315c260-902e-4934-b14d-74eec081acd3' User entered 'No (N)'	System	01 Sep 2020 21:44:39
	System	01 Sep 2020 21:44:39

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:44:38', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b315c260-902e-4934-b14d-74eec081acd3'	System	01 Sep 2020 21:44:39
User entered '01 Sep 2020 15:44'	System	01 Sep 2020 21:44:39

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 6'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:48:31', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1838d9-b39b-4678-a74b-8a77f99104cf' User entered 'Yes (Y)'	System	03 Sep 2020 01:48:55
	System	03 Sep 2020 01:48:55

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:48:39', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1838d9-b39b-4678-a74b-8a77f99104cf' User entered '95.7'	System	03 Sep 2020 01:48:55
	System	03 Sep 2020 01:48:55

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:48:44', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1838d9-b39b-4678-a74b-8a77f99104cf' User entered 'No (N)'	System	03 Sep 2020 01:48:55
	System	03 Sep 2020 01:48:55

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:48:51', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fe1838d9-b39b-4678-a74b-8a77f99104cf' User entered '02 Sep 2020 19:48'	System	03 Sep 2020 01:48:55
	System	03 Sep 2020 01:48:55

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 7'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:37:35', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e4fc0c2d-c1ec-4651-a01d-c07b21299d09'	System	03 Sep 2020 22:38:01
User entered 'Yes (Y)'	System	03 Sep 2020 22:38:01

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:37:45', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e4fc0c2d-c1ec-4651-a01d-c07b21299d09' User entered '96.9'	System	03 Sep 2020 22:38:01
	System	03 Sep 2020 22:38:01

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:37:52', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e4fc0c2d-c1ec-4651-a01d-c07b21299d09'	System	03 Sep 2020 22:38:01
User entered 'No (N)'	System	03 Sep 2020 22:38:01

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:37:59', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e4fc0c2d-c1ec-4651-a01d-c07b21299d09' User entered '03 Sep 2020 16:37'	System	03 Sep 2020 22:38:01
	System	03 Sep 2020 22:38:01

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:15:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '261db9b4-0b97-432e-9e47-069ab9e54dc8' User entered 'None (1)'	System	28 Aug 2020 21:16:05
	System	28 Aug 2020 21:16:05

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:15:46', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '261db9b4-0b97-432e-9e47-069ab9e54dc8' User entered 'No (N)'	System	28 Aug 2020 21:16:05
	System	28 Aug 2020 21:16:05

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:15:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '261db9b4-0b97-432e-9e47-069ab9e54dc8' User entered 'No (N)'	System	28 Aug 2020 21:16:05
	System	28 Aug 2020 21:16:05

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:15:57', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '261db9b4-0b97-432e-9e47-069ab9e54dc8' User entered 'None (1)'	System	28 Aug 2020 21:16:05
	System	28 Aug 2020 21:16:05

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:02', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '261db9b4-0b97-432e-9e47-069ab9e54dc8'	System	28 Aug 2020 21:16:05
User entered '28 Aug 2020 15:16'	System	28 Aug 2020 21:16:05

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 15:02'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 17:32'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:11', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b48293b0-73e4-41b6-a789-8c29e3d5604a' User entered 'None (1)'	System	29 Aug 2020 17:12:39
	System	29 Aug 2020 17:12:39

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:15', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b48293b0-73e4-41b6-a789-8c29e3d5604a' User entered 'No (N)'	System	29 Aug 2020 17:12:39
	System	29 Aug 2020 17:12:39

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:24', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b48293b0-73e4-41b6-a789-8c29e3d5604a' User entered 'No (N)'	System	29 Aug 2020 17:12:39
	System	29 Aug 2020 17:12:39

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:31', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b48293b0-73e4-41b6-a789-8c29e3d5604a' User entered 'None (1)'	System	29 Aug 2020 17:12:39
	System	29 Aug 2020 17:12:39

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:36', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b48293b0-73e4-41b6-a789-8c29e3d5604a' User entered '29 Aug 2020 11:12'	System	29 Aug 2020 17:12:39
	System	29 Aug 2020 17:12:39

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 18:27'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 2'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:14', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '59dbea3f-4ca2-4e1c-8ba0-add533b17746' User entered 'None (1)'	System	30 Aug 2020 06:01:45
	System	30 Aug 2020 06:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:22', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '59dbea3f-4ca2-4e1c-8ba0-add533b17746'	System	30 Aug 2020 06:01:45
User entered 'No (N)'	System	30 Aug 2020 06:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '59dbea3f-4ca2-4e1c-8ba0-add533b17746'	System	30 Aug 2020 06:01:45
User entered 'No (N)'	System	30 Aug 2020 06:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '59dbea3f-4ca2-4e1c-8ba0-add533b17746' User entered 'None (1)'	System	30 Aug 2020 06:01:45
	System	30 Aug 2020 06:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:42', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '59dbea3f-4ca2-4e1c-8ba0-add533b17746' User entered '30 Aug 2020 00:01'	System	30 Aug 2020 06:01:45
	System	30 Aug 2020 06:01:45

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 3'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:01:48', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4c4b6a1a-45c3-4195-a584-fa3eb47b33f1' User entered 'None (1)'	System	30 Aug 2020 18:02:19
	System	30 Aug 2020 18:02:19

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:01:58', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4c4b6a1a-45c3-4195-a584-fa3eb47b33f1' User entered 'No (N)'	System	30 Aug 2020 18:02:19
	System	30 Aug 2020 18:02:19

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:05', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4c4b6a1a-45c3-4195-a584-fa3eb47b33f1' User entered 'No (N)'	System	30 Aug 2020 18:02:19
	System	30 Aug 2020 18:02:19

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4c4b6a1a-45c3-4195-a584-fa3eb47b33f1' User entered 'None (1)'	System	30 Aug 2020 18:02:19
	System	30 Aug 2020 18:02:19

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:17', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4c4b6a1a-45c3-4195-a584-fa3eb47b33f1' User entered '30 Aug 2020 12:02'	System	30 Aug 2020 18:02:19
	System	30 Aug 2020 18:02:19

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 4'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:29', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '721ac186-cf22-46c2-8857-e61b42771eb4' User entered 'None (1)'	System	31 Aug 2020 18:25:53
	System	31 Aug 2020 18:25:53

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:33', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '721ac186-cf22-46c2-8857-e61b42771eb4' User entered 'No (N)'	System	31 Aug 2020 18:25:53
	System	31 Aug 2020 18:25:53

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:39', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '721ac186-cf22-46c2-8857-e61b42771eb4' User entered 'No (N)'	System	31 Aug 2020 18:25:53
	System	31 Aug 2020 18:25:53

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:43', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '721ac186-cf22-46c2-8857-e61b42771eb4' User entered 'None (1)'	System	31 Aug 2020 18:25:53
	System	31 Aug 2020 18:25:53

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:52', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '721ac186-cf22-46c2-8857-e61b42771eb4' User entered '31 Aug 2020 12:25'	System	31 Aug 2020 18:25:53
	System	31 Aug 2020 18:25:53

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 5'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:44:47', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a6aca27b-7749-4b59-946c-7042968e48ce' User entered 'None (1)'	System	01 Sep 2020 21:45:27
	System	01 Sep 2020 21:45:27

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:44:51', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a6aca27b-7749-4b59-946c-7042968e48ce' User entered 'No (N)'	System	01 Sep 2020 21:45:27
	System	01 Sep 2020 21:45:27

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:44:57', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a6aca27b-7749-4b59-946c-7042968e48ce' User entered 'No (N)'	System	01 Sep 2020 21:45:27
	System	01 Sep 2020 21:45:27

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:45:04', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a6aca27b-7749-4b59-946c-7042968e48ce' User entered 'None (1)'	System	01 Sep 2020 21:45:27
	System	01 Sep 2020 21:45:27

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:45:20', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a6aca27b-7749-4b59-946c-7042968e48ce' User entered '01 Sep 2020 15:45'	System	01 Sep 2020 21:45:27
	System	01 Sep 2020 21:45:27

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 6'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:49:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4353580f-b2a2-4b1e-83d3-3b528d430f88'	System	03 Sep 2020 01:50:01
User entered 'None (1)'	System	03 Sep 2020 01:50:01

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:49:09', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4353580f-b2a2-4b1e-83d3-3b528d430f88'	System	03 Sep 2020 01:50:01
User entered 'No (N)'	System	03 Sep 2020 01:50:01

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:49:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4353580f-b2a2-4b1e-83d3-3b528d430f88' User entered 'No (N)'	System	03 Sep 2020 01:50:01
	System	03 Sep 2020 01:50:01

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:49:44', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4353580f-b2a2-4b1e-83d3-3b528d430f88'	System	03 Sep 2020 01:50:01
User entered 'None (1)'	System	03 Sep 2020 01:50:01

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:49:57', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '4353580f-b2a2-4b1e-83d3-3b528d430f88' User entered '02 Sep 2020 19:49'	System	03 Sep 2020 01:50:01
	System	03 Sep 2020 01:50:01

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 7'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:08', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '11f4144e-43de-47ce-a9cb-57cd12a3fead'	System	03 Sep 2020 22:38:32
User entered 'None (1)'	System	03 Sep 2020 22:38:32

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '11f4144e-43de-47ce-a9cb-57cd12a3fead'	System	03 Sep 2020 22:38:32
User entered 'No (N)'	System	03 Sep 2020 22:38:32

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:19', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '11f4144e-43de-47ce-a9cb-57cd12a3fead'	System	03 Sep 2020 22:38:32
User entered 'No (N)'	System	03 Sep 2020 22:38:32

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:24', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '11f4144e-43de-47ce-a9cb-57cd12a3fead' User entered 'None (1)'	System	03 Sep 2020 22:38:32
	System	03 Sep 2020 22:38:32

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:30', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '11f4144e-43de-47ce-a9cb-57cd12a3fead' User entered '03 Sep 2020 16:38'	System	03 Sep 2020 22:38:32
	System	03 Sep 2020 22:38:32

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:11', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '963f2783-8ff6-43e9-8c00-6e5125099fde' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:15', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '963f2783-8ff6-43e9-8c00-6e5125099fde' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:20', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '963f2783-8ff6-43e9-8c00-6e5125099fde' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:23', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '963f2783-8ff6-43e9-8c00-6e5125099fde' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:26', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '963f2783-8ff6-43e9-8c00-6e5125099fde' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:29', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '963f2783-8ff6-43e9-8c00-6e5125099fde' User entered 'None (0)'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:34', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '963f2783-8ff6-43e9-8c00-6e5125099fde'	System	28 Aug 2020 21:16:45
User entered 'No (N)'	System	28 Aug 2020 21:16:45

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-28T15:16:42', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '963f2783-8ff6-43e9-8c00-6e5125099fde' User entered '28 Aug 2020 15:16'	System	28 Aug 2020 21:16:45
	System	28 Aug 2020 21:16:45

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 15:02'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 17:32'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:43', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '031d00d0-1df6-43b8-9236-5a374a32a211' User entered 'None (0)'	System	29 Aug 2020 17:13:16
	System	29 Aug 2020 17:13:16

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:46', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '031d00d0-1df6-43b8-9236-5a374a32a211' User entered 'None (0)'	System	29 Aug 2020 17:13:16
	System	29 Aug 2020 17:13:16

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:50', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '031d00d0-1df6-43b8-9236-5a374a32a211' User entered 'None (0)'	System	29 Aug 2020 17:13:16
	System	29 Aug 2020 17:13:16

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:12:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '031d00d0-1df6-43b8-9236-5a374a32a211' User entered 'None (0)'	System	29 Aug 2020 17:13:16
	System	29 Aug 2020 17:13:16

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:13:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '031d00d0-1df6-43b8-9236-5a374a32a211' User entered 'None (0)'	System	29 Aug 2020 17:13:16
	System	29 Aug 2020 17:13:16

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:13:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '031d00d0-1df6-43b8-9236-5a374a32a211' User entered 'None (0)'	System	29 Aug 2020 17:13:16
	System	29 Aug 2020 17:13:16

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:13:08', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '031d00d0-1df6-43b8-9236-5a374a32a211' User entered 'No (N)'	System	29 Aug 2020 17:13:16
	System	29 Aug 2020 17:13:16

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-29T11:13:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '031d00d0-1df6-43b8-9236-5a374a32a211' User entered '29 Aug 2020 11:13'	System	29 Aug 2020 17:13:16
	System	29 Aug 2020 17:13:16

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '28 Aug 2020 18:27'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 2'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:50', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '842785ec-6ef6-4a07-96f6-14274ed12c60' User entered 'None (0)'	System	30 Aug 2020 06:02:22
	System	30 Aug 2020 06:02:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '842785ec-6ef6-4a07-96f6-14274ed12c60' User entered 'None (0)'	System	30 Aug 2020 06:02:22
	System	30 Aug 2020 06:02:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:56', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '842785ec-6ef6-4a07-96f6-14274ed12c60' User entered 'None (0)'	System	30 Aug 2020 06:02:22
	System	30 Aug 2020 06:02:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:01:59', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '842785ec-6ef6-4a07-96f6-14274ed12c60' User entered 'None (0)'	System	30 Aug 2020 06:02:22
	System	30 Aug 2020 06:02:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:02:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '842785ec-6ef6-4a07-96f6-14274ed12c60' User entered 'None (0)'	System	30 Aug 2020 06:02:22
	System	30 Aug 2020 06:02:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:02:06', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '842785ec-6ef6-4a07-96f6-14274ed12c60' User entered 'None (0)'	System	30 Aug 2020 06:02:22
	System	30 Aug 2020 06:02:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:02:15', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '842785ec-6ef6-4a07-96f6-14274ed12c60' User entered 'No (N)'	System	30 Aug 2020 06:02:22
	System	30 Aug 2020 06:02:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T00:02:19', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '842785ec-6ef6-4a07-96f6-14274ed12c60' User entered '30 Aug 2020 00:02'	System	30 Aug 2020 06:02:22
	System	30 Aug 2020 06:02:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 3'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:24', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7a3a4e2d-fd30-493a-b354-05f92599df4e' User entered 'None (0)'	System	30 Aug 2020 18:02:55
	System	30 Aug 2020 18:02:55

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:28', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7a3a4e2d-fd30-493a-b354-05f92599df4e' User entered 'None (0)'	System	30 Aug 2020 18:02:55
	System	30 Aug 2020 18:02:55

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7a3a4e2d-fd30-493a-b354-05f92599df4e' User entered 'None (0)'	System	30 Aug 2020 18:02:55
	System	30 Aug 2020 18:02:55

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7a3a4e2d-fd30-493a-b354-05f92599df4e' User entered 'None (0)'	System	30 Aug 2020 18:02:55
	System	30 Aug 2020 18:02:55

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:40', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7a3a4e2d-fd30-493a-b354-05f92599df4e' User entered 'None (0)'	System	30 Aug 2020 18:02:55
	System	30 Aug 2020 18:02:55

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:43', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7a3a4e2d-fd30-493a-b354-05f92599df4e' User entered 'None (0)'	System	30 Aug 2020 18:02:55
	System	30 Aug 2020 18:02:55

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:49', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7a3a4e2d-fd30-493a-b354-05f92599df4e' User entered 'No (N)'	System	30 Aug 2020 18:02:55
	System	30 Aug 2020 18:02:55

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-30T12:02:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '7a3a4e2d-fd30-493a-b354-05f92599df4e' User entered '30 Aug 2020 12:02'	System	30 Aug 2020 18:02:55
	System	30 Aug 2020 18:02:55

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 4'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:25:58', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c758a5fc-74b5-48f6-8a5e-31c551096805' User entered 'None (0)'	System	31 Aug 2020 18:26:28
	System	31 Aug 2020 18:26:28

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:26:02', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c758a5fc-74b5-48f6-8a5e-31c551096805' User entered 'None (0)'	System	31 Aug 2020 18:26:28
	System	31 Aug 2020 18:26:28

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:26:06', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c758a5fc-74b5-48f6-8a5e-31c551096805' User entered 'None (0)'	System	31 Aug 2020 18:26:28
	System	31 Aug 2020 18:26:28

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:26:10', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c758a5fc-74b5-48f6-8a5e-31c551096805' User entered 'None (0)'	System	31 Aug 2020 18:26:28
	System	31 Aug 2020 18:26:28

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:26:13', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c758a5fc-74b5-48f6-8a5e-31c551096805' User entered 'None (0)'	System	31 Aug 2020 18:26:28
	System	31 Aug 2020 18:26:28

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:26:16', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c758a5fc-74b5-48f6-8a5e-31c551096805' User entered 'None (0)'	System	31 Aug 2020 18:26:28
	System	31 Aug 2020 18:26:28

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:26:20', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c758a5fc-74b5-48f6-8a5e-31c551096805'	System	31 Aug 2020 18:26:28
User entered 'No (N)'	System	31 Aug 2020 18:26:28

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-08-31T12:26:25', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'c758a5fc-74b5-48f6-8a5e-31c551096805' User entered '31 Aug 2020 12:26'	System	31 Aug 2020 18:26:28
	System	31 Aug 2020 18:26:28

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 5'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:45:48', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9410d19f-ccb5-4386-8f35-796c0a8d5f5e' User entered 'None (0)'	System	01 Sep 2020 21:46:49
	System	01 Sep 2020 21:46:49

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:45:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9410d19f-ccb5-4386-8f35-796c0a8d5f5e' User entered 'None (0)'	System	01 Sep 2020 21:46:49
	System	01 Sep 2020 21:46:49

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:46:07', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9410d19f-ccb5-4386-8f35-796c0a8d5f5e' User entered 'None (0)'	System	01 Sep 2020 21:46:49
	System	01 Sep 2020 21:46:49

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9410d19f-ccb5-4386-8f35-796c0a8d5f5e' User entered 'None (0)'	System	01 Sep 2020 21:46:49
	System	01 Sep 2020 21:46:49

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:46:16', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9410d19f-ccb5-4386-8f35-796c0a8d5f5e' User entered 'None (0)'	System	01 Sep 2020 21:46:49
	System	01 Sep 2020 21:46:49

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:46:19', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9410d19f-ccb5-4386-8f35-796c0a8d5f5e' User entered 'None (0)'	System	01 Sep 2020 21:46:49
	System	01 Sep 2020 21:46:49

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:46:29', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9410d19f-ccb5-4386-8f35-796c0a8d5f5e' User entered 'No (N)'	System	01 Sep 2020 21:46:49
	System	01 Sep 2020 21:46:49

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-01T15:46:46', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '9410d19f-ccb5-4386-8f35-796c0a8d5f5e' User entered '01 Sep 2020 15:46'	System	01 Sep 2020 21:46:49
	System	01 Sep 2020 21:46:49

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 6'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:50:03', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b97d4d2-47d3-4c76-b64d-c7e0a9ebae52' User entered 'None (0)'	System	03 Sep 2020 01:50:59
	System	03 Sep 2020 01:50:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:50:08', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b97d4d2-47d3-4c76-b64d-c7e0a9ebae52' User entered 'None (0)'	System	03 Sep 2020 01:50:59
	System	03 Sep 2020 01:50:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:50:15', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b97d4d2-47d3-4c76-b64d-c7e0a9ebae52' User entered 'None (0)'	System	03 Sep 2020 01:50:59
	System	03 Sep 2020 01:50:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:50:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b97d4d2-47d3-4c76-b64d-c7e0a9ebae52' User entered 'None (0)'	System	03 Sep 2020 01:50:59
	System	03 Sep 2020 01:50:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:50:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b97d4d2-47d3-4c76-b64d-c7e0a9ebae52' User entered 'None (0)'	System	03 Sep 2020 01:50:59
	System	03 Sep 2020 01:50:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:50:41', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b97d4d2-47d3-4c76-b64d-c7e0a9ebae52' User entered 'None (0)'	System	03 Sep 2020 01:50:59
	System	03 Sep 2020 01:50:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:50:49', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b97d4d2-47d3-4c76-b64d-c7e0a9ebae52'	System	03 Sep 2020 01:50:59
User entered 'No (N)'	System	03 Sep 2020 01:50:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-02T19:50:56', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '0b97d4d2-47d3-4c76-b64d-c7e0a9ebae52' User entered '02 Sep 2020 19:50'	System	03 Sep 2020 01:50:59
	System	03 Sep 2020 01:50:59

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	28 Aug 2020 21:03:22
User entered 'Day 7'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '89b96d6c-03ca-44ce-9659-12f6523b27bf' User entered 'None (0)'	System	03 Sep 2020 22:39:14
	System	03 Sep 2020 22:39:14

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:41', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '89b96d6c-03ca-44ce-9659-12f6523b27bf' User entered 'None (0)'	System	03 Sep 2020 22:39:14
	System	03 Sep 2020 22:39:14

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:50', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '89b96d6c-03ca-44ce-9659-12f6523b27bf' User entered 'None (0)'	System	03 Sep 2020 22:39:14
	System	03 Sep 2020 22:39:14

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:53', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '89b96d6c-03ca-44ce-9659-12f6523b27bf' User entered 'None (0)'	System	03 Sep 2020 22:39:14
	System	03 Sep 2020 22:39:14

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:38:58', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '89b96d6c-03ca-44ce-9659-12f6523b27bf' User entered 'None (0)'	System	03 Sep 2020 22:39:14
	System	03 Sep 2020 22:39:14

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:39:01', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '89b96d6c-03ca-44ce-9659-12f6523b27bf' User entered 'None (0)'	System	03 Sep 2020 22:39:14
	System	03 Sep 2020 22:39:14

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

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 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:39:06', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '89b96d6c-03ca-44ce-9659-12f6523b27bf' User entered 'No (N)'	System	03 Sep 2020 22:39:14
	System	03 Sep 2020 22:39:14

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-09-03T16:39:10', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '89b96d6c-03ca-44ce-9659-12f6523b27bf' User entered '03 Sep 2020 16:39'	System	03 Sep 2020 22:39:14
	System	03 Sep 2020 22:39:14

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:03:22

US3332001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:08:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:03:22

US3332001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 15:54:25
		05 Sep 2020 00:24:59

US3332001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:54:33
User entered '4 Sep 2020'	(b) (4), (b) (6)	05 Sep 2020 00:24:59

US3332001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:54:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Sep 2020 00:24:59

US3332001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:15:15
User entered empty.	(b) (4), (b) (6)	05 Sep 2020 00:24:59

US3332001

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:54:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 00:25:03

US3332001

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	05 Sep 2020 00:25:03

US3332001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:54:52
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	14 Sep 2020 15:35:50

US3332001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 15:54:54
User entered '11 Sep 2020'	Ty Henry (b) (4)	14 Sep 2020 15:35:50

US3332001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:54:56
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4) (b) (4)	14 Sep 2020 15:35:50

US3332001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:15:26
User entered empty.	Ty Henry (b) (4) (b) (4)	14 Sep 2020 15:35:50

US3332001

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:55:06
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	14 Sep 2020 15:36:11

US3332001

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	14 Sep 2020 15:36:11

US3332001

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:05:28
User entered 'Yes (Y)'	Colby Bostock (b) (4)	18 Sep 2020 17:22:33

US3332001

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:05:30
User entered '18 Sep 2020'	Colby Bostock (b) (4)	18 Sep 2020 17:22:33

US3332001

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:05:33
User entered 'Contact Made (CONTACT MADE)'	Colby Bostock (b) (4)	18 Sep 2020 17:22:33

US3332001

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:15:34
User entered empty.	Colby Bostock (b) (4) (b) (4)	18 Sep 2020 17:22:33

US3332001

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:05:48
User entered 'Yes (Y)'	Colby Bostock (b) (4)	18 Sep 2020 17:22:37

US3332001

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	18 Sep 2020 17:22:37

US3332001

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:05:54
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:24:21

US3332001

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:05:57
User entered '22 Sep 2020'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:24:21

US3332001

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:05:59
User entered 'Clinic (Clinic)'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:24:21

US3332001

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'VISIT3'	System	22 Sep 2020 18:24:21

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:02
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:07:05
User entered '22 Sep 2020'	Ty Henry (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:07
User entered '11:25'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '22 Sep 2020 11:25'	System	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:09
User entered '97.9' F	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:11
User entered 'Oral (Oral)'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:15:47
User entered empty.	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:25
User entered '73'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'bpm'	System	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:27
User entered '16'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'breaths/min'	System	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:28
User entered '124'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:30
User entered '71'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'mmHg'	System	22 Sep 2020 18:25:14

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39

US3332001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39

US3332001

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:44
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:26

US3332001

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:07:46
User entered '22 Sep 2020'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:26

US3332001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:08:22
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:52

US3332001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:08:24
User entered '22 Sep 2020'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:52

US3332001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:08:25
User entered '11:40'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:52

US3332001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered '22 Sep 2020 11:40'	System	22 Sep 2020 18:25:52

US3332001

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:04:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:09:03
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	22 Sep 2020 18:25:57

US3332001

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	22 Sep 2020 18:25:57

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 64'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-03T12:13:25', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b425a355-9898-4d3e-83a6-ea55a0f758f3'	System	03 Oct 2020 18:13:58
User entered 'No (N)'	System	03 Oct 2020 18:13:58

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-03T12:13:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b425a355-9898-4d3e-83a6-ea55a0f758f3'	System	03 Oct 2020 18:13:58
User entered 'No (N)'	System	03 Oct 2020 18:13:58

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-03T12:13:54', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b425a355-9898-4d3e-83a6-ea55a0f758f3' User entered '03 Oct 2020 12:13:54'	System	03 Oct 2020 18:13:58
	System	03 Oct 2020 18:13:58

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 71'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-10T09:08:09', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '20f882c9-21b8-48bf-a217-ac1cd67adc43' User entered 'No (N)'	System	10 Oct 2020 15:09:01
	System	10 Oct 2020 15:09:01

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-10T09:08:46', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '20f882c9-21b8-48bf-a217-ac1cd67adc43'	System	10 Oct 2020 15:09:01
User entered 'No (N)'	System	10 Oct 2020 15:09:01

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-10T09:08:57', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '20f882c9-21b8-48bf-a217-ac1cd67adc43' User entered '10 Oct 2020 09:08:57'	System	10 Oct 2020 15:09:01
	System	10 Oct 2020 15:09:01

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 78'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-17T08:46:02', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'df592424-fb14-4dec-9455-e9d73f09904e' User entered 'No (N)'	System	17 Oct 2020 14:46:18
	System	17 Oct 2020 14:46:18

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-17T08:46:13', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'df592424-fb14-4dec-9455-e9d73f09904e'	System	17 Oct 2020 14:46:18
User entered 'No (N)'	System	17 Oct 2020 14:46:18

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-10-17T08:46:16', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'df592424-fb14-4dec-9455-e9d73f09904e' User entered '17 Oct 2020 08:46:16'	System	17 Oct 2020 14:46:18
	System	17 Oct 2020 14:46:18

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 92'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-02T09:05:06', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '16b0912e-bf3b-469b-9eba-30b538fe9292'	System	02 Nov 2020 16:05:51
User entered 'No (N)'	System	02 Nov 2020 16:05:51

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-02T09:05:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '16b0912e-bf3b-469b-9eba-30b538fe9292'	System	02 Nov 2020 16:05:51
User entered 'No (N)'	System	02 Nov 2020 16:05:51

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-02T09:05:48', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '16b0912e-bf3b-469b-9eba-30b538fe9292' User entered '02 Nov 2020 09:05:48'	System	02 Nov 2020 16:05:51
	System	02 Nov 2020 16:05:51

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 99'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-07T00:02:45', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a96dac8a-2436-4e09-a831-55fd5d319930' User entered 'No (N)'	System	07 Nov 2020 07:03:07
	System	07 Nov 2020 07:03:07

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-07T00:02:59', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a96dac8a-2436-4e09-a831-55fd5d319930' User entered 'No (N)'	System	07 Nov 2020 07:03:07
	System	07 Nov 2020 07:03:07

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-07T00:03:04', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'a96dac8a-2436-4e09-a831-55fd5d319930' User entered '07 Nov 2020 00:03:04'	System	07 Nov 2020 07:03:07
	System	07 Nov 2020 07:03:07

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered 'Day 106'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-16T12:01:16', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '369e1c71-404c-45a0-a77a-86e044a664b4' User entered 'No (N)'	System	16 Nov 2020 19:01:49
	System	16 Nov 2020 19:01:49

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-16T12:01:35', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '369e1c71-404c-45a0-a77a-86e044a664b4' User entered 'No (N)'	System	16 Nov 2020 19:01:49
	System	16 Nov 2020 19:01:49

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6EBB2D9A-FC10-4A54-BF20-9F1746124D2C)', Time: '2020-11-16T12:01:46', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '369e1c71-404c-45a0-a77a-86e044a664b4' User entered '16 Nov 2020 12:01:46'	System	16 Nov 2020 19:01:49
	System	16 Nov 2020 19:01:49

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 23:48:00

US3332001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:22:08
Data entry locked.	System	03 Aug 2020 23:48:00
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 23:48:00

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-09T11:28:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '55ccd949-c25c-4c6a-b492-7cf41b0cfc44'	System	09 Jan 2021 18:29:09
User entered 'No (N)'	System	09 Jan 2021 18:29:09

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-09T11:28:42', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '55ccd949-c25c-4c6a-b492-7cf41b0cfc44'	System	09 Jan 2021 18:29:09
User entered 'No (N)'	System	09 Jan 2021 18:29:09

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-09T11:28:55', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '55ccd949-c25c-4c6a-b492-7cf41b0cfc44'	System	09 Jan 2021 18:29:09
User entered '09 Jan 2021 11:28:55'	System	09 Jan 2021 18:29:09

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:44:49', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered 'Yes (Y)'	System	13 Jan 2021 19:47:29
	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:44:58', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered 'No (N)'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:45:09', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered 'Yes (Y)'	System	13 Jan 2021 19:47:29
	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '1'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '1'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:12', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '0'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Please 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:20', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b'	System	13 Jan 2021 19:47:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:46:31', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered 'No (N)'	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-13T12:47:17', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '498a3b12-23eb-4c67-a849-f8f393f6866b' User entered '13 Jan 2021 12:47:17'	System	13 Jan 2021 19:47:29
	System	13 Jan 2021 19:47:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-20T12:46:27', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ae1b2943-7845-448f-86ce-eb2ac878f982'	System	20 Jan 2021 19:46:48
User entered 'No (N)'	System	20 Jan 2021 19:46:48

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-20T12:46:37', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ae1b2943-7845-448f-86ce-eb2ac878f982'	System	20 Jan 2021 19:46:48
User entered 'No (N)'	System	20 Jan 2021 19:46:48

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-20T12:46:43', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'ae1b2943-7845-448f-86ce-eb2ac878f982' User entered '20 Jan 2021 12:46:43'	System	20 Jan 2021 19:46:48
	System	20 Jan 2021 19:46:48

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-28T09:56:11', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e12e970e-9155-4938-af7b-0ea928907e43' User entered 'No (N)'	System	28 Jan 2021 16:56:57

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-28T09:56:25', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e12e970e-9155-4938-af7b-0ea928907e43'	System	28 Jan 2021 16:56:57
User entered 'No (N)'	System	28 Jan 2021 16:56:57

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-01-28T09:56:34', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'e12e970e-9155-4938-af7b-0ea928907e43' User entered '28 Jan 2021 09:56:34'	System	28 Jan 2021 16:56:57
	System	28 Jan 2021 16:56:57

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-03T00:23:17', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2cc1fe9b-bd64-4f2f-bcde-ea96f55ecb64' User entered 'No (N)'	System	03 Feb 2021 07:23:38
	System	03 Feb 2021 07:23:38

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-03T00:23:27', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2cc1fe9b-bd64-4f2f-bcde-ea96f55ecb64' User entered 'No (N)'	System	03 Feb 2021 07:23:38

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-03T00:23:32', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '2cc1fe9b-bd64-4f2f-bcde-ea96f55ecb64' User entered '03 Feb 2021 00:23:32'	System	03 Feb 2021 07:23:38
	System	03 Feb 2021 07:23:38

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-10T09:59:35', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '619e5aae-d93c-4a5c-b2fe-50bd8f40b72b' User entered 'Yes (Y)'	System	10 Feb 2021 17:00:15
	System	10 Feb 2021 17:00:15

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-10T09:59:41', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '619e5aae-d93c-4a5c-b2fe-50bd8f40b72b'	System	10 Feb 2021 17:00:15
User entered 'No (N)'	System	10 Feb 2021 17:00:15

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-10T09:59:51', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '619e5aae-d93c-4a5c-b2fe-50bd8f40b72b' User entered 'No (N)'	System	10 Feb 2021 17:00:15
	System	10 Feb 2021 17:00:15

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-10T10:00:05', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '619e5aae-d93c-4a5c-b2fe-50bd8f40b72b'	System	10 Feb 2021 17:00:15
User entered 'No (N)'	System	10 Feb 2021 17:00:15

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-10T10:00:10', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '619e5aae-d93c-4a5c-b2fe-50bd8f40b72b' User entered '10 Feb 2021 10:00:10'	System	10 Feb 2021 17:00:15
	System	10 Feb 2021 17:00:15

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-17T07:09:38', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '1cec2f45-9af4-42fd-8d21-4e82f7762550' User entered 'No (N)'	System	17 Feb 2021 14:09:59
	System	17 Feb 2021 14:09:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-17T07:09:49', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '1cec2f45-9af4-42fd-8d21-4e82f7762550'	System	17 Feb 2021 14:09:59
User entered 'No (N)'	System	17 Feb 2021 14:09:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-17T07:09:54', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '1cec2f45-9af4-42fd-8d21-4e82f7762550' User entered '17 Feb 2021 07:09:54'	System	17 Feb 2021 14:09:59
	System	17 Feb 2021 14:09:59

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-24T08:44:04-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fc0f4a1a-ba11-473a-8da9-0cdd3d6ed59c' User entered 'No (N)'	System	24 Feb 2021 15:44:25

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-24T08:44:13-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fc0f4a1a-ba11-473a-8da9-0cdd3d6ed59c'	System	24 Feb 2021 15:44:25
User entered 'No (N)'	System	24 Feb 2021 15:44:25

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-02-24T08:44:22-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'fc0f4a1a-ba11-473a-8da9-0cdd3d6ed59c'	System	24 Feb 2021 15:44:25
User entered '24 Feb 2021 15:44:22'	System	24 Feb 2021 15:44:25

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-03T08:33:02-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '93111127-abb0-41b6-8e15-75459d6a9148'	System	03 Mar 2021 15:33:19
User entered 'No (N)'	System	03 Mar 2021 15:33:19

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-03T08:33:10-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '93111127-abb0-41b6-8e15-75459d6a9148'	System	03 Mar 2021 15:33:19
User entered 'No (N)'	System	03 Mar 2021 15:33:19

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-03T08:33:17-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '93111127-abb0-41b6-8e15-75459d6a9148'	System	03 Mar 2021 15:33:19
User entered '03 Mar 2021 08:33:17'	System	03 Mar 2021 15:33:19

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-10T18:44:19-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'eb06ea94-8a8a-48cc-8d3b-10a71d2bfa5d'	System	11 Mar 2021 01:44:37
User entered 'No (N)'	System	11 Mar 2021 01:44:37

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-10T18:44:24-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'eb06ea94-8a8a-48cc-8d3b-10a71d2bfa5d'	System	11 Mar 2021 01:44:37
User entered 'No (N)'	System	11 Mar 2021 01:44:37

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-10T18:44:32-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'eb06ea94-8a8a-48cc-8d3b-10a71d2bfa5d' User entered '10 Mar 2021 18:44:32'	System	11 Mar 2021 01:44:37
	System	11 Mar 2021 01:44:37

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-17T08:19:12-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5103a1c0-1276-4f3b-a879-4233ff223f07'	System	17 Mar 2021 14:19:28
User entered 'No (N)'	System	17 Mar 2021 14:19:28

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-17T08:19:18-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5103a1c0-1276-4f3b-a879-4233ff223f07'	System	17 Mar 2021 14:19:28
User entered 'No (N)'	System	17 Mar 2021 14:19:28

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-17T08:19:25-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '5103a1c0-1276-4f3b-a879-4233ff223f07'	System	17 Mar 2021 14:19:28
User entered '17 Mar 2021 08:19:25'	System	17 Mar 2021 14:19:28

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-26T12:01:27-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '34e405d7-3f0f-4378-abf6-e4524f4de2e7'	System	26 Mar 2021 18:01:51
User entered 'No (N)'	System	26 Mar 2021 18:01:51

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-26T12:01:34-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '34e405d7-3f0f-4378-abf6-e4524f4de2e7'	System	26 Mar 2021 18:01:51
User entered 'No (N)'	System	26 Mar 2021 18:01:51

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-26T12:01:38-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '34e405d7-3f0f-4378-abf6-e4524f4de2e7' User entered '26 Mar 2021 12:01:38'	System	26 Mar 2021 18:01:51
	System	26 Mar 2021 18:01:51

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-31T09:46:11-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '910d8f52-320a-46b2-8e0c-729ad2afd88d'	System	31 Mar 2021 15:46:29
User entered 'No (N)'	System	31 Mar 2021 15:46:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-31T09:46:16-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '910d8f52-320a-46b2-8e0c-729ad2afd88d'	System	31 Mar 2021 15:46:29
User entered 'No (N)'	System	31 Mar 2021 15:46:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-31T09:46:25-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '910d8f52-320a-46b2-8e0c-729ad2afd88d'	System	31 Mar 2021 15:46:29
User entered '31 Mar 2021 09:46:25'	System	31 Mar 2021 15:46:29

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-07T08:41:11-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b6e3ea80-6e60-4fb5-9418-c8fdde3c7256'	System	07 Apr 2021 14:41:26
User entered 'No (N)'	System	07 Apr 2021 14:41:26

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-07T08:41:18-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b6e3ea80-6e60-4fb5-9418-c8fdde3c7256'	System	07 Apr 2021 14:41:26
User entered 'No (N)'	System	07 Apr 2021 14:41:26

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-07T08:41:22-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'b6e3ea80-6e60-4fb5-9418-c8fdde3c7256'	System	07 Apr 2021 14:41:26
User entered '07 Apr 2021 08:41:22'	System	07 Apr 2021 14:41:26

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-14T08:58:32-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'd51aaf2d-f55b-456e-91bb-d4e1a5e0fbfd' User entered 'No (N)'	System	14 Apr 2021 14:58:49

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-14T08:58:39-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'd51aaf2d-f55b-456e-91bb-d4e1a5e0fbfd' User entered 'No (N)'	System	14 Apr 2021 14:58:49

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-14T08:58:44-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'd51aaf2d-f55b-456e-91bb-d4e1a5e0fbfd' User entered '14 Apr 2021 08:58:44'	System	14 Apr 2021 14:58:49
	System	14 Apr 2021 14:58:49

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-21T10:10:38-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cc7c7e2c-3b4c-4e7f-9290-d4e20694d5ad'	System	21 Apr 2021 16:13:40
User entered 'No (N)'	System	21 Apr 2021 16:13:40

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-21T10:10:47-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cc7c7e2c-3b4c-4e7f-9290-d4e20694d5ad'	System	21 Apr 2021 16:13:40
User entered 'No (N)'	System	21 Apr 2021 16:13:40

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-21T10:10:50-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: 'cc7c7e2c-3b4c-4e7f-9290-d4e20694d5ad' User entered '21 Apr 2021 10:10:50'	System	21 Apr 2021 16:13:40
	System	21 Apr 2021 16:13:40

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-28T09:19:20-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '182c3adb-1f10-49da-95b7-4b1fa040e1ec' User entered 'No (N)'	System	28 Apr 2021 22:24:24
	System	28 Apr 2021 22:24:24

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Have you been exposed to someone with 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 (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-28T09:19:26-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '182c3adb-1f10-49da-95b7-4b1fa040e1ec'	System	28 Apr 2021 22:24:24
User entered 'No (N)'	System	28 Apr 2021 22:24:24

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-04-28T09:19:30-06:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '182c3adb-1f10-49da-95b7-4b1fa040e1ec'	System	28 Apr 2021 22:24:24
User entered '28 Apr 2021 09:19:30'	System	28 Apr 2021 22:24:24

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 12:12:42

US3332001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:08:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:12:42
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 12:12:42

US3332001

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:08:14

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 05:59:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-03T08:33:26-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '8d42b78c-3c91-4dff-955c-2fb57116dd55'	System	03 Mar 2021 15:33:34
User entered 'No (N)'	System	03 Mar 2021 15:33:34

US3332001

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:08:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:59:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5F742494-1043-4BD5-818F-1AD00FA4C428)', Time: '2021-03-03T08:33:31-07:00', User OID: 'PatientReportedOutcome (US3332001)', ODM File OID: '8d42b78c-3c91-4dff-955c-2fb57116dd55' User entered '03 Mar 2021 08:33:31'	System	03 Mar 2021 15:33:34
	System	03 Mar 2021 15:33:34

US3332001

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	04 Nov 2020 16:21:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 15:59:00

US3332001

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:53
User entered '21 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 15:59:00

US3332001

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:21:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Oct 2020 15:59:00

US3332001

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:16:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:59:00

US3332001

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	04 Nov 2020 16:22:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 15:59:05

US3332001

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:53:39
User entered 'I'	System	22 Oct 2020 15:59:05

US3332001

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.		25 Feb 2021 19:07:52
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4)	
	Ashley Bragg (b) (4)	23 Nov 2020 21:37:51
	(b) (4)	

US3332001

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.		25 Feb 2021 19:07:52
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '23 Nov 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:37:51

US3332001

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.		25 Feb 2021 19:07:52
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:37:51

US3332001

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.		25 Feb 2021 19:07:52
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:37:51

US3332001

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	23 Nov 2020 21:37:56

US3332001

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered 'I'	System	23 Nov 2020 21:37:56

US3332001

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.		11 Mar 2021 20:35:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Dec 2020 18:11:34

US3332001

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '23 Dec 2020'	Ashley Bragg (b) (4)	23 Dec 2020 18:11:34

US3332001

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Dec 2020 18:11:34

US3332001

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Dec 2020 18:11:34

US3332001

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Dec 2020 18:11:37

US3332001

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered 'I'	System	23 Dec 2020 18:11:37

US3332001

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:43:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:16:03

US3332001

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:43:03
Query 'Per CDM: Safety Call Day 179 (1) visit date 22JAN2021 Is same as Safety Call OL-D8 (1)visit date 22JAN2021 which is incorrect.Kindly consider to verify and update data appropriately else please clarify.Thank you. ' canceled (Site from DM).		14 Apr 2021 16:21:00
User opened query 'Per CDM: Safety Call Day 179 (1) visit date 22JAN2021 Is same as Safety Call OL-D8 (1)visit date 22JAN2021 which is incorrect.Kindly consider to verify and update data appropriately else please clarify.Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 11:36:35
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:16:03

US3332001

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:43:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:16:03

US3332001

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:43:03
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:16:03

US3332001

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 20:35:55
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:16:10

US3332001

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered 'I'	System	25 Jan 2021 19:16:10

US3332001

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:42

US3332001

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:42

US3332001

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:42

US3332001

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered 'VISIT4'	System	12 Feb 2021 17:15:42

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'No (N)'	Ashley Bragg (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered empty.	System	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered empty.	System	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered empty.	System	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered empty.	System	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered empty.	System	30 Mar 2021 22:56:13

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38

US3332001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38

US3332001

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:49

US3332001

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:49

US3332001

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	18 Mar 2021 18:48:25

US3332001

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '10 Feb 2021'	Kenadie Hamblin (b) (4)	18 Mar 2021 18:48:25

US3332001

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '11:35'	Kenadie Hamblin (b) (4)	18 Mar 2021 18:48:25

US3332001

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered '10 Feb 2021 11:35'	System	18 Mar 2021 18:48:25

US3332001

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 17:15:55

US3332001

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:46:38
User entered 'I'	System	12 Feb 2021 17:15:55

US3332001

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	23 Mar 2021 20:15:12

US3332001

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '23 Mar 2021'	Ashley Bragg (b) (4)	23 Mar 2021 20:15:12

US3332001

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Contact Made (CONTACT MADE)'	Ashley Bragg (b) (4)	23 Mar 2021 20:15:12

US3332001

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	Ashley Bragg (b) (4)	23 Mar 2021 20:15:12

US3332001

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	23 Mar 2021 20:15:16

US3332001

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:33
User entered 'I'	System	23 Mar 2021 20:15:16

US3332001

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:28:55
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	23 Apr 2021 20:04:26
	(b) (4)	

US3332001

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:28:55
	(b) (4)	
User entered '23 Apr 2021'	Ashley Bragg (b) (4)	23 Apr 2021 20:04:26
	(b) (4)	

US3332001

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Apr 2021 20:04:26

US3332001

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:28:55
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	23 Apr 2021 20:04:26
	(b) (4)	

US3332001

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:28:55
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	23 Apr 2021 20:04:30
	(b) (4)	

US3332001

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 20:04:30

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:14

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:09
User entered '29 Sep 2020'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 15:46:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:14

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:11
User entered '15:30'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 15:46:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:14

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:28
User entered '29 Sep 2020 15:30'	System	01 Oct 2020 15:46:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:14

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:12
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 15:46:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:08:14

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:28
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:14
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 15:46:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
Query 'Per ETRTR: Please consider adding Symptoms since onset of AE 28Sep20, thanks.' canceled (Site from CRA).		22 Oct 2020 17:03:28
User opened query 'Per ETRTR: Please consider adding Symptoms since onset of AE 28Sep20, thanks.' (Site from CRA).		11 Oct 2020 00:45:06
User entered 'Day 2 (Day 2)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Per CDM; it appears that Contact date is 29SEP2020 yet date of first symptom is 01OCT2020. Please reconcile or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Nov 2020 18:36:38
DataPoint Verified.		26 Oct 2020 21:40:29
Query 'Per CDM; it appears that Contact date is 29SEP2020 yet date of first symptom is 01OCT2020. Please reconcile or clarify' answered with 'site added day 1 info onto page 2 of the symptom log ' (Site from DM).		26 Oct 2020 21:36:51
User opened query 'Per CDM; it appears that Contact date is 29SEP2020 yet date of first symptom is 01OCT2020. Please reconcile or clarify' (Site from DM).		25 Oct 2020 11:03:34
User entered '01 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		26 Oct 2020 21:39:35
DataPoint Verified.		26 Oct 2020 21:39:33
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:36
User entered '96'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:38
User entered '97.6' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:41
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:51
User entered 'Mild (Mild)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:56
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:54
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:40:00
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:39:58
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:40:13
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:40:09
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:40:15
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:40:17
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:40:19
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:40:20
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:52:55

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 3 (Day 3)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:10
User entered '02 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		26 Oct 2020 21:41:27
DataPoint Verified.		26 Oct 2020 21:41:26
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:29
User entered '96'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:31
User entered '97.5' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:34
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:36
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:47
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:53
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:55
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:41:56
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:45:06
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:45:07
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:45:09
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:45:12
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:45:14
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:19
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:54:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 4 (Day 4)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:26
User entered '03 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:28
User entered '96'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:30
User entered '98.2' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:32
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:34
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:36
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:41
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:53
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:56
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:58
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:31:59
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:02
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:04
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:55:21

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 5 (Day 5)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:10
User entered '04 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:12
User entered '97'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:23
User entered '98.4' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:31
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:32
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:35
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:39
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:42
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:47
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:55
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:58
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:32:59
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:01
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:02
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:04
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 19:58:40

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 6 (Day 6)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:17
User entered '05 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:19
User entered '95'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:20
User entered '97.4' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:22
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:23
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:26
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:28
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:30
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:32
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:33
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:42
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:47
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:51
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:53
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:00:32

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 7 (Day 7)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:33:59
User entered '06 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		26 Oct 2020 22:34:03
DataPoint Verified.		26 Oct 2020 22:34:01
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:05
User entered '95'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:11
User entered '97.5' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:13
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:14
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:16
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:18
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:20
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:22
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:24
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:26
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:27
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:29
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:31
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:33
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:38
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:39
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:41
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:01:50

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 8 (Day 8)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:54
User entered '07 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:56
User entered '96'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:58
User entered '97.8' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:34:59
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:02
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:04
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:06
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:07
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:09
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:10
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:12
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:15
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:16
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:18
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:19
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:21
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:23
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:25
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:26
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:05:09

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 9 (Day 9)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:37
User entered '08 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:40
User entered '95'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:42
User entered '97.9' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:51
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:53
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:54
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:56
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:35:59
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:01
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:03
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:05
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:06
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:09
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:11
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:13
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 10 (Day 10)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:19
User entered '09 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:21
User entered '96'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:33
User entered '97.7' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:35
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:38
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:41
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:54
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:56
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:36:58
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:00
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:02
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:04
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:06
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:06:45

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 11 (Day 11)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:14
User entered '10 Oct 2020'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:17
User entered '96'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:29
User entered '97.5' F	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:30
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:32
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:33
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:35
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:40
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:42
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:45
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:37:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:38:10
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:43:51
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:43:53
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:43:55
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:43:56
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:43:58
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:38:48

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 12 (Day 12)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:16
User entered '11 Oct 2020'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:17
User entered '96'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:20
User entered '97.2' F	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:25
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:27
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:30
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:32
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:34
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:36
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:38
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:41
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:43
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:48
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:54
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:56
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:44:57
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:01

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 13 (Day 13)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:05
User entered '12 Oct 2020'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:15
User entered '96'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:16
User entered '96.1' F	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:19
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:21
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:28
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:31
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:35
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:37
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:39
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:41
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:44
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:46
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:49
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:50
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:52
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:54
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:56
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:45:58
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:40:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 14 (Day 14)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:04
User entered '13 Oct 2020'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:07
User entered '97'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:08
User entered '96.8' F	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:10
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:11
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:13
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:15
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:16
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:19
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:20
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:22
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:23
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:25
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:28
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:30
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:33
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:34
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:36
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:46:38
User entered 'None (None)'	Ty Henry (b) (4) (b) (4)	13 Oct 2020 22:42:41

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:00:49
User entered 'Day 15 (Day 15)'		20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:46:57
User entered '14 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:47:01
User entered '97'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:47:02
User entered '95.5' F	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:47:07
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:47:08
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:47:10
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:47:11
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:47:14
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:47:15
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:47:17
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:47:19
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:47:21
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:47:22
User entered 'None (None)' reason for change: Data Entry Error		20 Oct 2020 04:04:54
User entered empty.		20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:47:24
User entered 'None (None)' reason for change: Data Entry Error		20 Oct 2020 04:04:54
User entered empty.		20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:47:25
User entered 'None (None)' reason for change: Data Entry Error		20 Oct 2020 04:04:54
User entered empty.		20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:47:27
User entered 'None (None)' reason for change: Data Entry Error		20 Oct 2020 04:04:54
User entered empty.		20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:47:29
User entered 'None (None)' reason for change: Data Entry Error		20 Oct 2020 04:04:54
User entered empty.		20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Oct 2020 22:47:31
User entered 'None (None)' reason for change: Data Entry Error		20 Oct 2020 04:04:54
User entered empty.		20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:47:33
User entered 'None (None)' reason for change: Data Entry Error		20 Oct 2020 04:04:54
User entered empty.		20 Oct 2020 04:04:04

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 18 (Day 18)' reason for change:	(b) (4)	27 Oct 2020 23:00:49
Data Entry Error	(b) (4), (b) (6)	
User entered 'Day 16 (Day 16)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 29OCT2020. Please reconcile or clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:50:50
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 29OCT2020. Please reconcile or clarify.' (Site from DM).		09 Nov 2020 03:29:31
DataPoint Verified.		26 Oct 2020 22:49:36
User entered '15 Oct 2020'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:37
User entered '0'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:38
User entered '97'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:40
User entered '95.3' F		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:42
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:44
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:46
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:47
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:49
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:50
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:52
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:49:54
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Oct 2020 22:49:58
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Oct 2020 22:50:00
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:50:02
User entered 'None (None)'		20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:50:03
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:50:05
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:50:07
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:50:08
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:50:10
User entered 'None (None)'	(b) (4), (b) (6)	20 Oct 2020 04:05:52

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Please verify and enter 30Sep2020. The symptom days will need to be updated on all lines respective to Day 1 of symptoms on 28Sep2020' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 02:08:09
Query 'Please verify and enter 30Sep2020. The symptom days will need to be updated on all lines respective to Day 1 of symptoms on 28Sep2020' answered with 'day 1 is the day sx started which was 9/28/20 so this is correct ' (Site from CRA).		27 Oct 2020 22:54:27
User opened query 'Please verify and enter 30Sep2020. The symptom days will need to be updated on all lines respective to Day 1 of symptoms on 28Sep2020' (Site from CRA).		27 Oct 2020 22:51:40
User closed query 'Please verify and enter 29Sep20 and 30Sep20 based on AEs that had previously been entered on AE log but were COVID symptoms.' (Site from CRA).		27 Oct 2020 22:51:40
Query 'Please verify and enter 29Sep20 and 30Sep20 based on AEs that had previously been entered on AE log but were COVID symptoms.' answered with 'UPDATED AND ADDED 28TH AND 29TH BUT NOW THE DAYS ARE OFF PLEASE ADVISE ' (Site from CRA).		27 Oct 2020 22:12:03
User opened query 'Please verify and enter 29Sep20 and 30Sep20 based on AEs that had previously been entered on AE log but were COVID symptoms.' (Site from CRA).		27 Oct 2020 04:24:02
User entered 'Day 1 (Day 1)'		20 Oct 2020 19:26:14

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Please verify if symptoms noted on AE log that were later removed should be added once the correct dates are added to log. 29-30Sep2020 AE noted subject experienced Fever, Cough, Fatigue, Headache, Body aches, Sore throat and vomiting. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 02:09:15
Query 'Please verify if symptoms noted on AE log that were later removed should be added once the correct dates are added to log. 29-30Sep2020 AE noted subject experienced Fever, Cough, Fatigue, Headache, Body aches, Sore throat and vomiting. Please reconcile.' answered with 'UPDATED' (Site from CRA).		27 Oct 2020 22:19:32
User opened query 'Please verify if symptoms noted on AE log that were later removed should be added once the correct dates are added to log. 29-30Sep2020 AE noted subject experienced Fever, Cough, Fatigue, Headache, Body aches, Sore throat and vomiting. Please reconcile.' (Site from CRA).		27 Oct 2020 04:25:32
DataPoint Verified.		26 Oct 2020 22:50:19
User entered '28 Sep 2020' reason for change: Data Entry Error		20 Oct 2020 19:32:13
User entered '29 Sep 2020'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (+), (b) (6)	26 Oct 2020 22:50:26
User entered missing code ND - Not Done.		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	26 Oct 2020 22:50:29
User entered missing code ND - Not Done.		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (+), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:50:31
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:11:37
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		27 Oct 2020 22:11:37
DataPoint Verified.		26 Oct 2020 22:50:33
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:50:34
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:50:35
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:50:37
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:50:39
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:15
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:16
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:18
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:19
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:21
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:23
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:25
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:11:37
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		27 Oct 2020 22:11:37
DataPoint Verified.		26 Oct 2020 22:52:26
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:29
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
DataPoint Un-verified.		27 Oct 2020 22:19:23
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:19:23
DataPoint Verified.		26 Oct 2020 22:52:30
User entered 'Not Done (Not Done)'		20 Oct 2020 19:26:14

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:05:19
User entered '29 Sep 2020'	(b) (4), (b) (6)	27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered '%'	System	27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '100.8' F	(b) (4), (b) (6)	27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User closed query 'Please verify as previous AE noted that cough was ongoing on 29Sep2020' (Site from CRA).		28 Oct 2020 02:08:58
Query 'Please verify as previous AE noted that cough was ongoing on 29Sep2020' answered with 'updated' (Site from CRA).		27 Oct 2020 23:02:07
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		27 Oct 2020 23:02:00
User opened query 'Please verify as previous AE noted that cough was ongoing on 29Sep2020' (Site from CRA).		27 Oct 2020 22:54:39
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'Severe (Severe)' reason for change:		27 Oct 2020 22:14:00
Data Entry Error		
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:27:55
DataPoint Un-verified.		10 Nov 2020 03:27:53
DataPoint Verified.		10 Nov 2020 03:05:19
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		27 Oct 2020 22:14:00
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		27 Oct 2020 22:14:00
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		27 Oct 2020 22:14:00
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:14:00
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'None (None)' reason for change: Data Entry Error		27 Oct 2020 22:21:23
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Nov 2020 03:05:19
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		27 Oct 2020 22:14:00
User entered 'Not Done (Not Done)'		27 Oct 2020 22:08:54

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered '30 Sep 2020'		27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:05:19
User entered 'l'	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User entered empty.	System	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:08:14

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:34
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:05:19
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 22:56:37

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Per GCL Lab Reconciliation requery: Swab: Thanks for your response. Per EDC, swab sample collected on 30-SEP-2020 is under Covid-19 Assessment visit & per PPD portal it is recorded under Convalescence Visit Day 28. Kindly confirm in site response for which visit swab sample was collected on 30-SEP-2020.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:30:33
Query 'Per GCL Lab Reconciliation requery: Swab: Thanks for your response. Per EDC, swab sample collected on 30-SEP-2020 is under Covid-19 Assessment visit & per PPD portal it is recorded under Convalescence Visit Day 28. Kindly confirm in site response for which visit swab sample was collected on 30-SEP-2020.' answered with 'sample collected on 9.30.20 was day 1 illness visit' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 15:29:06
User opened query 'Per GCL Lab Reconciliation requery: Swab: Thanks for your response. Per EDC, swab sample collected on 30-SEP-2020 is under Covid-19 Assessment visit & per PPD portal it is recorded under Convalescence Visit Day 28. Kindly confirm in site response for which visit swab sample was collected on 30-SEP-2020.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:26:49
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-SEP-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 30-SEP-2020 is reported under "Convalescence Visit Day 28" in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:26:49

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-SEP-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 30-SEP-2020 is reported under "Convalescence Visit Day 28" in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response.' answered with 'i confirm date of collection is correct as 9.30.2020' (Site from DM).	Colby Bostock (b) (4) (b) (4)	12 Nov 2020 18:15:37
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-SEP-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 30-SEP-2020 is reported under "Convalescence Visit Day 28" in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response.' (Site from DM).	(b) (4), (b) (6) (b) (4)	12 Nov 2020 06:25:26
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	12 Oct 2020 15:54:30
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	09 Oct 2020 22:40:57
User entered '6 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:32
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:46:52
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:54:36
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 'Data to be updated.' (Site from System).	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:34
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	09 Oct 2020 20:09:18
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:41
User entered '30 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:43
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:27
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:46:17
DataPoint Un-verified.		20 Oct 2020 19:34:57
User entered 'No (N)' reason for change: Data Entry Error		20 Oct 2020 19:34:57
DataPoint Verified.		12 Oct 2020 15:54:57
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:27
DataPoint Un-verified.		20 Oct 2020 19:34:57
User entered empty; reason for change Data Entry Error		20 Oct 2020 19:34:57
DataPoint Verified.		12 Oct 2020 15:54:59
User entered 'Labcorp'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:05:27
DataPoint Un-verified.		20 Oct 2020 19:34:57
User entered empty; reason for change Data Entry Error		20 Oct 2020 19:34:57
DataPoint Verified.		12 Oct 2020 15:55:01
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:08:14

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:41
User entered 'I'	System	09 Oct 2020 20:09:18

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:25:47
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:25:49
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:25:58
User entered 'No (N)'	Ty Henry (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:26:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 20:11:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 20:11:54
User entered 'No (N)' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:54
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 20:11:44
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:26:17
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:26:23
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User closed query 'Re-query: Per previous instructions this field is to be completed. Vital signs present showing BP of 88/61 which meets criteria to be entered on severity page regardless of outside factors. Please update section as required.' (Site from CRA).		06 Nov 2020 17:35:45
Query 'Re-query: Per previous instructions this field is to be completed. Vital signs present showing BP of 88/61 which meets criteria to be entered on severity page regardless of outside factors. Please update section as required.' answered with 'added' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 15:25:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:24:54
User opened query 'Re-query: Per previous instructions this field is to be completed. Vital signs present showing BP of 88/61 which meets criteria to be entered on severity page regardless of outside factors. Please update section as required.' (Site from CRA).		06 Nov 2020 04:42:40
User closed query 'Please verify as Illness Day 1 vitals note BP of 88/61' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 04:42:40
Query 'Please verify as Illness Day 1 vitals note BP of 88/61' answered with 'CRC performing Illness Day 1 vitals and Investigator recall patient took hypertension medication within 1 hour of Illness Day 1 visit. Subject contacted and confirmed that they usually take blood pressure medication between 0700 and 1030, but they took it late that day. At Illness Day 1 visit, investigator confirmed subject was not experiencing symptoms corresponding to the low blood pressure reading.' (Site from CRA).	Megan Grimmatt (b) (4) (b) (4)	05 Nov 2020 22:52:15
User opened query 'Please verify as Illness Day 1 vitals note BP of 88/61' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:41:43
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:08:14

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered '30 Sep 2020' reason for change: Data Entry Error		09 Nov 2020 19:55:46
User entered '29 Sep 2020' reason for change: Data Entry Error		06 Nov 2020 17:22:36
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered '30 Sep 2020' reason for change: Data Entry Error		09 Nov 2020 19:55:46
User entered '29 Sep 2020' reason for change: Data Entry Error		06 Nov 2020 17:22:36
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered 'No (N)' reason for change: Data Entry Error		06 Nov 2020 17:22:36
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered 'No (N)' reason for change: Data Entry Error		06 Nov 2020 17:22:36
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:22:36
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:22:36
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:22:36
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:22:36
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

US3332001

Folder: Covid-19 Assessment 29 Sep 2020

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:26:43
User entered 'No (N)'	Ty Henry (b) (4)	09 Oct 2020 20:11:44

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Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:06:10
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 20:11:44

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Folder: Covid-19 Assessment 29 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:08:14

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:08:54
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:06:30
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 15:21:22

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User accepted default value 'Day 3 (Day 3)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:13:36
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:13:38
User entered '02 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User accepted default value 'Day 5 (Day 5)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:13:49
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:13:50
User entered '05 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User accepted default value 'Day 7 (Day 7)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:13:58
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:13:59
User entered '07 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User accepted default value 'Day 9 (Day 9)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:14:07
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:14:08
User entered '09 Oct 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User accepted default value 'Day 14 (Day 14)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:14:20
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 16:43:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 16:43:09
User entered 'Yes (Y)' reason for change: New Information	Ty Henry (b) (4) (b) (4)	15 Oct 2020 16:43:09
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 22:12:45
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:14:21
User entered '12 Oct 2020' reason for change: Data Entry Error	Ty Henry (b) (4)	15 Oct 2020 16:43:09
User entered empty.	(b) (4) Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User accepted default value 'Day 21 (Day 21)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:14:39
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 04:01:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 04:01:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 04:01:57
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 22:12:45
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:14:40
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 04:01:57
User entered empty.	Ty Henry (b) (4)	09 Oct 2020 22:12:45
	(b) (4)	

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:14

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User accepted default value 'Day 28 (Day 28)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:14

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:19:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 19:39:13
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 21:47:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 21:47:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:47:40
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 22:12:45
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same sample is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 05:34:36
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same sample is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'CONTACTED LAB TO CORRECT DATA TO DAY 28. CORRECT AS ENTERED HERE' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 16:06:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same sample is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:20:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:19:47
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 19:39:13
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:12:45

US3332001

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:46
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:55:25
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:05:56

US3332001

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:46
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:55:27
User entered '30 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:05:56

US3332001

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:46
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:55:29
User entered 'Clinic (Clinic)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:05:56

US3332001

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:46
User entered 'SICKD1'	System	09 Oct 2020 22:05:56

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:47:54
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:47:56
User entered '30 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:48:30
User entered '13:10'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User entered '30 Sep 2020 13:10'	System	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:48:26
User entered '69.0' in	Ty Henry (b) (4)	09 Oct 2020 22:08:54
DataPoint set to visible.	(b) (4) System	09 Oct 2020 22:05:56

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:48:24
User entered '145' lb	Ty Henry (b) (4)	09 Oct 2020 22:08:54
DataPoint set to visible.	(b) (4) System	09 Oct 2020 22:05:56

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:48:21
User entered '98.7' F	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:48:32
User entered 'Oral (Oral)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:11:45
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:48:56
User entered '98'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User entered 'bpm'	System	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:49:02
User entered '16'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User entered 'breaths/min'	System	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Per ETRTR: Please confirm clinical significance on Low Blood Pressure and consider reporting within Adverse Event page if applicable, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:49:35
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 21:49:31
Query 'Per ETRTR: Please confirm clinical significance on Low Blood Pressure and consider reporting within Adverse Event page if applicable, thanks.' answered with 'Not clinically significant per source.' (Site from CRA).	Ty Henry (b) (4) (b) (4)	15 Oct 2020 16:50:16
User opened query 'Per ETRTR: Please confirm clinical significance on Low Blood Pressure and consider reporting within Adverse Event page if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	11 Oct 2020 00:43:19
User entered '88'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User entered 'mmHg'	System	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:50:00
User entered '61'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51
User entered 'mmHg'	System	09 Oct 2020 22:08:54

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51

US3332001

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:51

US3332001

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:55
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:50:26
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:09:40

US3332001

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:55
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:50:28
User entered '30 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:09:40

US3332001

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:14

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:50:46
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:11:06

US3332001

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:24:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:50:47
User entered '30 Sep 2020'	Ty Henry (b) (4) (b) (4)	09 Oct 2020 22:11:06

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 29OCT2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 29OCT2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 06:09:07
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 29OCT2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 29OCT2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' answered with 'accession number is- 1f602997346 and it has been shipped' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 20:17:27
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 29OCT2020 is recorded under Convalescence Visit Day 28 in GCL, however, the swab sample for 29OCT2020 is missing in EDC. Please confirm if this sample should be recorded in the Covid-19 Assessment folder and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:49:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:15:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 19:37:22

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:15:54
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 19:37:22

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[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 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:15:57
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Oct 2020 19:37:22

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered 'SICKD28'	System	29 Oct 2020 19:37:22

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:16:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:16:28
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:16:34
User entered '11:45'	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered '29 Oct 2020 11:45'	System	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:16:38
User entered '70.0' in	(b) (4), (b) (6)	29 Oct 2020 19:38:32
DataPoint set to visible.	System	29 Oct 2020 19:37:22

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:16:42
User entered '145.0' lb	(b) (4), (b) (6)	29 Oct 2020 19:38:32
DataPoint set to visible.	System	29 Oct 2020 19:37:22

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:16:46
User entered '98.1' F	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:16:51
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:03:36
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:17:17
User entered '83'	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered 'bpm'	System	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:17:19
User entered '14'	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered 'breaths/min'	System	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:17:23
User entered '136'	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered 'mmHg'	System	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:17:26
User entered '84'	(b) (4), (b) (6)	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User entered 'mmHg'	System	29 Oct 2020 19:38:32

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:17:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 19:38:42

US3332001

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:17:48
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 19:38:42

US3332001

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:08:14

[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 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:18:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 19:38:56

US3332001

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:08:14

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:47
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 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 07:33:20
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 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 due to kit shortage which was okayed by sponsor. date correct as entered ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:57:00
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 29 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)	12 Nov 2020 10:33:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:18:14
User entered '29 Oct 2020'		29 Oct 2020 19:38:56

US3332001

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:45:57

US3332001

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:45:57

US3332001

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:05
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Clinic (Clinic)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:45:57

US3332001

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

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 23:45:57

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:46:10

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:02:40
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:42:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:16:28

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:46:10

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:02:40
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 10:43:26
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:43:15
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 18:42:50
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:32:27
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:16:28

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:46:10

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Placebo (Placebo)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:46:10

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:07:31
User entered 'Placebo (Placebo)'	Bradley Young (b) (4)	12 Jan 2021 23:46:10

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:07:31
User entered 'Placebo (Placebo)'	Bradley Young (b) (4)	12 Jan 2021 23:46:10

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:36
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:46:10

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '1'	System	12 Jan 2021 23:46:10

US3332001

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

Form: Unblinding

Generated On: 09 Jun 2021 17:08:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'I'	System	12 Jan 2021 23:46:10

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:13
	Bradley Young (b) (4)	

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:13
	Bradley Young (b) (4)	

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered empty.	System	12 Jan 2021 23:48:13
DataPoint set to visible.	System	12 Jan 2021 23:46:10

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:13
	Bradley Young (b) (4)	

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:13
	Bradley Young (b) (4)	

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered empty.	System	12 Jan 2021 23:48:13
DataPoint set to visible.	System	12 Jan 2021 23:46:10

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User accepted default value 'Pre-Dose (PREDOSE)'	Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '16:00'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '12 Jan 2021 16:00'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '98.2' F	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Oral (Oral)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:13
	Bradley Young (b) (4)	

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '85'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'bpm'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '16'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'breaths/min'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '129'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '74'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:13
	Bradley Young (b) (4)	

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:13
	Bradley Young (b) (4)	

US3332001

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:08:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered empty.	System	12 Jan 2021 23:48:13
DataPoint set to visible.	System	12 Jan 2021 23:46:10

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User accepted default value 'Post-Dose (POSTDOSE)'	Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '16:37'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '12 Jan 2021 16:37'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '97.8' F	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Oral (Oral)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:13
	Bradley Young (b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '80'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'bpm'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '14'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'breaths/min'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '117'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '69'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:13

US3332001

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	12 Jan 2021 23:48:13

US3332001

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:21

US3332001

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:21

US3332001

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:00
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:39

US3332001

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

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:00
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:39
	Bradley Young (b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

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)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:00
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4)	12 Jan 2021 23:48:39
	Bradley Young (b) (4)	

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mRNA-1273'	System	12 Jan 2021 23:48:39
DataPoint set to visible.	System	12 Jan 2021 23:46:10

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:00
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:39

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:00
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '16:11'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:39

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '12 Jan 2021 16:11'	System	12 Jan 2021 23:48:39

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:00
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:48:39

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:00
User entered 'ONCE'	System	12 Jan 2021 23:48:39

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 23:48:39

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:20
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:49:08

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:20
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:49:08

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:20
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '15:35'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:49:08

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '12 Jan 2021 15:35'	System	12 Jan 2021 23:49:08

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:26
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:49:21

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:14

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:26
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '12 Jan 2021'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:49:21

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:26
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '15:32'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:49:21

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:08:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '12 Jan 2021 15:32'	System	12 Jan 2021 23:49:21

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:38
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	12 Jan 2021 23:49:26

US3332001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'I'	System	12 Jan 2021 23:49:26

US3332001

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:15:30

US3332001

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:16:22
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 19:15:30

US3332001

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:15:30

US3332001

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:48
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:15:30

US3332001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:53
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:15:40

US3332001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'I'	System	25 Jan 2021 19:15:40

US3332001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '1'	System	25 Jan 2021 19:15:40
DataPoint set to visible.	System	25 Jan 2021 19:15:40

US3332001

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:19:02
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:12:49

US3332001

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:19:02
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:12:49

US3332001

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:19:02
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:12:49

US3332001

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'OLD29'	System	08 Feb 2021 22:12:49

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '13:50'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '8 Feb 2021 13:50'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '69'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'bpm'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '14'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'breaths/min'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '134'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '83'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:08:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '15:19'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '8 Feb 2021 15:19'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '74'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'bpm'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'breaths/min'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '111'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '72'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	08 Feb 2021 22:25:17

US3332001

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:12:57

US3332001

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:22:24
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:12:57

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

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)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mRNA-1273'	System	08 Feb 2021 22:23:02
DataPoint set to visible.	System	25 Jan 2021 19:15:40

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '14:47'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '8 Feb 2021 14:47'	System	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:08
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:08
User entered 'ONCE'	System	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:08:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 22:23:02

US3332001

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:23
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 22:25:22

US3332001

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'I'	System	08 Feb 2021 22:25:22

US3332001

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	Colby Bostock (b) (4)	12 Feb 2021 22:24:02

US3332001

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	18 Feb 2021 21:08:19
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	18 Feb 2021 21:08:19
User entered '18 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 21:08:19
Amendment Manager: User opened query 'OL Safety System Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		16 Feb 2021 20:32:02
User entered '12 Feb 2021'	Colby Bostock (b) (4)	12 Feb 2021 22:24:02
	(b) (4)	

US3332001

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colby Bostock (b) (4) (b) (4)	12 Feb 2021 22:24:02

US3332001

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:08:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:39
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	12 Feb 2021 22:24:02

US3332001

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:56
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 21:07:50

US3332001

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:08:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'I'	System	18 Feb 2021 21:07:50

US3332001

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:21:33

US3332001

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '5 Mar 2021'	(b) (4) Kenadie Hamblin (b) (4)	05 Mar 2021 22:21:33

US3332001

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Clinic (Clinic)'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:21:33

US3332001

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:08:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'OLD57'	System	05 Mar 2021 22:21:33

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '5 Mar 2021'	(b) (4) Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '14:07'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '5 Mar 2021 14:07'	System	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '98.5' F	Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Oral (Oral)'	(b) (4) Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered empty.	(b) (4) Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '81'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'bpm'	System	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '16'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'breaths/min'	System	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '117'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '63'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered 'mmHg'	System	05 Mar 2021 22:22:07

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02

US3332001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:08:14

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02

US3332001

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:16

US3332001

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:08:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '5 Mar 2021'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:16

US3332001

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered 'Yes (Y)'	(b) (4) Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:30

US3332001

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '5 Mar 2021'	(b) (4) Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:30

US3332001

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
User entered '14:24'	Kenadie Hamblin (b) (4)	05 Mar 2021 22:22:30

US3332001

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:08:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:02
User entered '5 Mar 2021 14:24'	System	05 Mar 2021 22:22:30

US3332001

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:08:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:20
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:56:36
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 15:57:33

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:18:24
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:45:50
User entered	System	02 Oct 2020 12:45:46
'USA-US202-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	02 Oct 2020 12:45:46

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:18:29
User closed query 'PV Query: As this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:18:52
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)	13 Oct 2020 21:00:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	13 Oct 2020 21:00:16
Data point term sent to Coder	System	13 Oct 2020 20:58:57
Query 'PV Query: As this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' answered with 'Updated.' (Site from Safety).	Ty Henry (b) (4)	13 Oct 2020 20:58:11
Coding entries removed.	(b) (4)	
	Ty Henry (b) (4)	13 Oct 2020 20:58:03
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4)	
	Ty Henry (b) (4)	13 Oct 2020 20:58:03
User opened query 'PV Query: As this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:01:52
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)	02 Oct 2020 00:53:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	02 Oct 2020 00:53:37
Data point term sent to Coder	System	02 Oct 2020 00:52:53
User entered 'SYMPTOMATIC COVID-19'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:18:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:18:39
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:18:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:18:42
User entered '30 Sep 2020' reason for change: Data Entry Error	Ty Henry (b) (4)	16 Oct 2020 19:28:40
	(b) (4)	
User entered '28 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:18:45
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Oct 2020 19:34:45
User entered 'No (N)' reason for change: New Information	Ty Henry (b) (4)	16 Oct 2020 19:34:45
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Oct 2020 19:34:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:18:52
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:17:30
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'Data updated.' (Site from Safety).	Ty Henry (b) (4)	16 Oct 2020 19:35:44
	(b) (4)	
User entered '02 Oct 2020' reason for change: New Information	Ty Henry (b) (4)	16 Oct 2020 19:34:31
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:01:05
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:18:58
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 16:36:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 16:36:13
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Ty Henry (b) (4)	06 Oct 2020 16:36:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Oct 2020 00:52:35
	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:19:01
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35
	(b) (4), (b) (6)	

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35
	(b) (4), (b) (6)	

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 00:52:35
	(b) (4), (b) (6)	

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 00:52:35
	(b) (4), (b) (6)	

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:19:06
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 00:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 00:52:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 00:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 00:52:35
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:19:10
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 00:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 00:52:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 00:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 00:52:35
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:19:12
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 00:52:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 00:52:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 00:52:53
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 00:52:35
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 15:30:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:30:02
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 15:29:24
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:11:49
User entered '1'		02 Oct 2020 00:52:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	07 Nov 2020 18:35:34
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	06 Nov 2020 15:29:31
' answered with 'updated' (Site from DM).		
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:29:24
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.		06 Nov 2020 09:55:21
' (Site from DM).		
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:11:49
User entered '0'		02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

US3332001

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 17:42:04
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 19:17:34
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Data updated.' (Site from Safety).	Ty Henry (b) (4)	16 Oct 2020 19:35:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	
	(b) (4)	16 Oct 2020 19:34:31
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 20:01:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	02 Oct 2020 00:52:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 00:52:35
	(b) (4), (b) (6)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:08:14

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:34:28
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:34:25
User entered 'SUBJECT'S NEPHEW IS SUSPECTED EXPOSURE' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:11:24
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'Subject's nephew is suspected exposure Subject took no medications and had no interventions ' (Site from Safety).		22 Oct 2020 16:09:43
User entered 'Subject's nephew is suspected exposure Subject took no medications and had no interventions' reason for change: Data Entry Error		22 Oct 2020 16:09:38
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.' answered with 'per subject, he took no medications and had no interventions ' (Site from Safety).		22 Oct 2020 16:04:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:05:41

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' canceled (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 13:05:27
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).		07 Oct 2020 20:02:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		07 Oct 2020 20:02:31
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).		07 Oct 2020 20:01:29
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including results of Covid-19 diagnostic test, symptoms log, and severity assessment. ' (Site from Safety).		07 Oct 2020 20:00:40
User entered empty.		02 Oct 2020 00:52:35

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Folder: Adverse Events

Form: Adverse Events (9)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 00:52:35

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:08:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 00:52:35

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03

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Folder: Adverse Events

Form: Adverse Events (10)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:15
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:13:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:13:25
Data point term sent to Coder	System	05 Nov 2020 19:20:31
User closed query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	05 Nov 2020 19:20:11
Query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'UPDATED' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 19:20:11
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 19:20:03
Coding entries removed.		05 Nov 2020 19:20:03
User entered 'CHEST TIGHTNESS ETIOLOGY UNKNOWN' reason for change: Data Entry Error		05 Nov 2020 19:20:03
User opened query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:46:25
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:31

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:02:35
Data point term sent to Coder	System	22 Oct 2020 16:01:45
User entered 'CHEST TIGHTNESS'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:38
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	04 Nov 2020 17:42:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:41
User entered '02 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User entered empty.	System	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:44
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:45
User entered '20 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User entered empty.	System	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:43:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:44:24
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 03:17:15
		22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 03:17:15
		22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:52
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:54
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:42:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:15
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 15:31:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:31:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 15:30:38
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 03:17:15
		22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:17:15
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:35:50
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'removed' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:30:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 15:30:38
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:55:02
User entered '1'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:43:03
User closed query ' Per CDM-Outcome is recorded as 'Recovered/Resolved ',however,end date of AE is not recorded.Kindly consider to verify and update data appropriately. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:18:45
Query ' Per CDM-Outcome is recorded as 'Recovered/Resolved ',however,end date of AE is not recorded.Kindly consider to verify and update data appropriately. ' answered with 'YES IT IS' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 21:59:19
User opened query ' Per CDM-Outcome is recorded as 'Recovered/Resolved ',however,end date of AE is not recorded.Kindly consider to verify and update data appropriately. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:50:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Oct 2020 16:01:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

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 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 03:17:15
		22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:15
User entered empty; reason for change Data Entry Error		22 Oct 2020 16:10:02
User entered 'Subject's nephew is suspected exposure Subject took no medications and had no interventions' reason for change: Data Entry Error		22 Oct 2020 16:09:14
User entered empty.		22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User entered '0'	System	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03
User entered 'I'	System	22 Oct 2020 16:01:00

US3332001

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:08:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:03

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:41:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:41:05
Data point term sent to Coder	System	23 Nov 2020 21:40:41
User entered 'Tooth infection'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '17 Nov 2020'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User entered empty.	System	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'No (N)'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '17 Nov 2020'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:08:14

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User entered empty.	System	23 Nov 2020 21:39:52

US3332001

Folder: Adverse Events

Form: Adverse Events (13)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 19:58:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 19:58:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Ashley Bragg (b) (4)	24 Nov 2020 19:58:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 21:39:52
User entered empty.	System	23 Nov 2020 21:39:52
	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'No (N)'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '0'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '0'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '0'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

Form: Adverse Events (13)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '0'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

Form: Adverse Events (13)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '0'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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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)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '0'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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Form: Adverse Events (13)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 19:58:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 19:58:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ashley Bragg (b) (4)	24 Nov 2020 19:58:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 21:39:52
User entered empty.	System	23 Nov 2020 21:39:52
	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	24 Nov 2020 19:58:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 19:58:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ashley Bragg (b) (4)	24 Nov 2020 19:58:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 21:39:52
User entered empty.	System	23 Nov 2020 21:39:52
	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query '	(b) (4) (b) (4), (b) (6)	30 Nov 2020 08:09:16
Per CDM: Per CCG pg.33,Action taken with investigational product is expected to be 'Not applicable' If adverse event started AFTER last dose.Please consider to update this field appropriately or else, clarify. Thank you. ' (Site from DM).		
Query '	(b) (4), (b) (6)	27 Nov 2020 15:27:14
Per CDM: Per CCG pg.33,Action taken with investigational product is expected to be 'Not applicable' If adverse event started AFTER last dose.Please consider to update this field appropriately or else, clarify. Thank you. ' answered with '.' (Site from DM).		
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	27 Nov 2020 15:27:07
reason for change: Data Entry Error		
User opened query '	(b) (4), (b) (6)	25 Nov 2020 10:21:32
Per CDM: Per CCG pg.33,Action taken with investigational product is expected to be 'Not applicable' If adverse event started AFTER last dose.Please consider to update this field appropriately or else, clarify. Thank you. ' (Site from DM).		
User entered 'None (NONE)'	Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:08:14

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 05:21:35
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'item corrected' (Site from DM).	Ashley Bragg (b) (4) (b) (4)	23 Dec 2020 18:13:38
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		23 Dec 2020 18:12:55
User entered '0' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	23 Dec 2020 18:12:55
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	23 Dec 2020 18:12:36
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 02:34:33
User entered '1'	Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

Form: Adverse Events (13)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '0'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

Form: Adverse Events (13)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '1' reason for change: Data Entry Error	(b) (4)	23 Dec 2020 18:12:36
User entered '0'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Ashley Bragg (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

Form: Adverse Events (13)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:39:52

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Folder: Adverse Events

Form: Adverse Events (13)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User entered '0'	System	23 Nov 2020 21:39:52

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Folder: Adverse Events

Form: Adverse Events (13)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16
User entered 'I'	System	23 Nov 2020 21:39:52

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Folder: Adverse Events

Form: Adverse Events (13)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:22:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:08:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:20
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 21:51:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 19:00:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:20:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: ENALAPRIL MALEATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:13:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:13:10
Data point term sent to Coder	System	13 Aug 2020 19:02:52
Data point term sent to Coder	System	13 Aug 2020 19:01:52
User entered 'Enalapril Maleate'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:20:24
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:20:26
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:02:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 19:02:21
User entered 'hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:02:21
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 19:01:46
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:07:43
	(b) (4)	
Signature has been broken.	Kenadie Hamblin (b) (4)	25 Feb 2021 20:51:43
	(b) (4)	
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:20:28
User entered '20'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:20:31
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:21:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:21:03
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User closed query 'per source, the correct date is 21 Mar 2018. please verify.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:30:17
Query 'per source, the correct date is 21 Mar 2018. please verify.' answered with 'updated' (Site from CRA).		27 Oct 2020 22:04:09
User entered '21 Mar 2018' reason for change: Data Entry Error		27 Oct 2020 22:04:03
User opened query 'per source, the correct date is 21 Mar 2018. please verify.' (Site from CRA).		27 Oct 2020 03:58:14
DataPoint Un-verified.		27 Oct 2020 03:56:49
DataPoint Verified.		26 Oct 2020 22:21:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		14 Aug 2020 00:50:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:01:46
User entered '07 Jul 2019'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:30:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 19:01:46
	(b) (4), (b) (6)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:21:34
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:01:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:21:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 01:33:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 01:33:09
Data point term sent to Coder	System	14 Aug 2020 01:31:41
User entered 'TRAZODONE'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:21:59
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:22:06
User entered 'INSOMNIA'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:22:10
User entered '50'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:22:11
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:31:32
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:22:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:31:32
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:22:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:22:30
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 10:20:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 01:37:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 01:31:32
User entered '26 Nov 2018'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:30:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:31:32
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:22:43
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 01:31:32

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:23:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 07:03:23
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 07:03:23
	(b) (4)	
Data point term sent to Coder	System	14 Aug 2020 01:39:50
User entered 'levothyroxine sodium'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:23:39
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:23:41
User entered 'acquired hypothyroidism'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:23:43
User entered '125'	(b) (4), (b) (6)	14 Aug 2020 01:39:39
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
User closed query '1MICROGRAMME =1 ug which is available in dropdown. Please verify.' (Site from CRA).		05 Nov 2020 18:01:50
Query '1MICROGRAMME =1 ug which is available in dropdown. Please verify.' answered with 'UPDATED' (Site from CRA).		05 Nov 2020 17:41:53
DataPoint Un-verified.		05 Nov 2020 17:41:39
User entered 'ug (ug)' reason for change: Data Entry Error		05 Nov 2020 17:41:39
User opened query '1MICROGRAMME =1 ug which is available in dropdown. Please verify.' (Site from CRA).		04 Nov 2020 23:00:54
DataPoint Verified.		26 Oct 2020 22:23:47
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		23 Oct 2020 09:12:40
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'UPDATED ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:14:09
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:14:03
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		13 Oct 2020 05:41:52
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
User closed query '1MICROGRAMME =1 ug which is available in dropdown. Please verify.' (Site from CRA).		05 Nov 2020 18:02:02
Query '1MICROGRAMME =1 ug which is available in dropdown. Please verify.' answered with 'UPDATED' (Site from CRA).		05 Nov 2020 17:41:50
DataPoint Un-verified.		05 Nov 2020 17:41:39
User entered empty; reason for change Data Entry Error		05 Nov 2020 17:41:39
User opened query '1MICROGRAMME =1 ug which is available in dropdown. Please verify.' (Site from CRA).		04 Nov 2020 23:00:26
User closed query 'Per CDM Requery:If dose unit is Other, Specify is given as 'MCG ',however, frequency 'MCG/UG 'is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify ' (Site from DM).		30 Oct 2020 05:32:49
Query 'Per CDM Requery:If dose unit is Other, Specify is given as 'MCG ',however, frequency 'MCG/UG 'is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify ' answered with 'not available from drop down for site ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:07:05
User opened query 'Per CDM Requery:If dose unit is Other, Specify is given as 'MCG ',however, frequency 'MCG/UG 'is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:13:38
User closed query 'Per CDM:If dose unit is Other, Specify is given as 'MCG ',however, frequency 'MICROGRAMME 'is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:28:57

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:23:06
Query 'Per CDM:If dose unit is Other, Specify is given as 'MCG ' ,however, frequency 'MICROGRAMME 'is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify' answered with 'NOT AVAILABLE TO SITE STAFF IN DROP DOWN' (Site from DM).		26 Oct 2020 22:04:11
User opened query 'Per CDM:If dose unit is Other, Specify is given as 'MCG ' ,however, frequency 'MICROGRAMME 'is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:15:02
Query 'Per DMR:If dose unit is Other, Specify is given as 'MCG ' ,however, frequency 'MICROGRAMME 'is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:14:47
User opened query 'Per DMR:If dose unit is Other, Specify is given as 'MCG ' ,however, frequency 'MICROGRAMME 'is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:14:39
User entered 'MCGS' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:14:03
User entered empty.		14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:23:16
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:23:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:39:39
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:23:24
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 10:20:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'correct as entered ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 01:39:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 01:39:39
User entered 'un UNK 2000'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:39:39
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:23:30
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:39:39
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 01:39:39

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:24:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 01:41:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 01:41:13
	(b) (4)	
Data point term sent to Coder	System	14 Aug 2020 01:40:51
User entered 'xanax'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:24:08
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:40:45
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:24:11
User entered 'insomnia'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:24:28
User entered '0.5'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:24:30
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:40:45
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:24:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:40:45
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:24:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:24:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 18:49:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Lindsey Bevan (b) (4)	15 Aug 2020 15:47:16
answered with 'Date entered is correct and added appropriately.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 01:40:45
User entered '26 Nov 2018'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:30:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:24:50
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 01:40:45

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:24:56
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: ALPROSTADIL;PAPAVERINE;PHENTOLAMINE, PRODUCTSYNONYM: TRIMIX [ALPROSTADIL;PAPAVERINE;PHENTOLAMINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 11:40:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 11:40:37
Data point term sent to Coder	System	08 Sep 2020 21:29:26
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	08 Sep 2020 21:29:12
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'Updated.' (Site from System).	Ty Henry (b) (4)	08 Sep 2020 21:29:12
User entered 'TRIMIX [Alprostadil, Papaverine, Phentolamine]' reason for change: Per Query Resolution	Ty Henry (b) (4)	08 Sep 2020 21:29:02
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)	17 Aug 2020 07:45:17
Data point term sent to Coder	System	14 Aug 2020 01:42:51
User entered 'trimix'	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:25:01
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:42:10
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:25:20
User entered 'low testosterone'	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ML as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:34:22
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ML as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'correct as entered' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:32:07
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of ML as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:45:45
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this combination medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:32:31
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this combination medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:05:47
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:05:05
User entered '200' reason for change: Data Entry Error		29 Oct 2020 17:05:05
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this combination medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).		28 Oct 2020 08:47:31
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:25:30
User entered '27'		14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:05:05
User entered 'mL (mL)' reason for change: Data Entry Error		29 Oct 2020 17:05:05
DataPoint Verified.		26 Oct 2020 22:25:32
User entered 'Other (OTHER)'		14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 17:05:05
User entered empty; reason for change Data Entry Error		29 Oct 2020 17:05:05
DataPoint Verified.		26 Oct 2020 22:25:38
User entered 'mcg'		14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:25:40
User entered 'as needed (PRN)'	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:25:46
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:25:50
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 18:49:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Lindsey Bevan (b) (4)	15 Aug 2020 15:47:36
answered with 'Date entered is correct and added appropriately.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 01:42:10
User entered 'un UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:25:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:42:10
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:25:57
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:42:10
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 01:42:10

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:26:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 01:45:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 01:45:10
	(b) (4)	
Data point term sent to Coder	System	14 Aug 2020 01:43:52
User entered 'testosterone'	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:26:07
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:26:09
User entered 'low testosterone'	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 750 mg, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		07 Nov 2020 18:34:32
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 750 mg, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:10:35
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 21:10:24
User entered '200' reason for change: Data Entry Error		06 Nov 2020 21:10:24
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 750 mg, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).		06 Nov 2020 10:45:25
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:26:13
User entered '1'		14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	06 Nov 2020 21:12:18
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	06 Nov 2020 21:10:24
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 21:10:24
User entered 'mg (mg)' reason for change: Data Entry Error		06 Nov 2020 21:10:24
DataPoint Verified.		26 Oct 2020 22:26:15
User entered 'Other (OTHER)'		14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
DataPoint Un-verified.		06 Nov 2020 21:12:18
User entered empty; reason for change Data Entry Error		06 Nov 2020 21:12:18
DataPoint Verified.		26 Oct 2020 22:26:18
User entered 'injection'		14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:26:20
User entered 'every week (QS)'	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 04:16:04
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:26:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 18:49:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Lindsey Bevan (b) (4)	15 Aug 2020 15:47:48
answered with 'Date entered is correct and added appropriately.' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 01:43:38
User entered 'un UNK 2017'	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 01:43:38
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:29:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:43:38
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:26:37
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	14 Aug 2020 01:43:38

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 19:49:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 19:49:20
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:26:54
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: DICLOFENAC SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 15:05:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 15:05:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:08:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:08:18
Data point term sent to Coder	System	14 Aug 2020 01:44:52
User entered 'diclofenac sodium'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:26:56
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:26:59
User entered 'actinic keratosis'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:27:02
User entered 'I'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:27:08
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:27:12
User entered 'application'	(b) (4), (b) (6)	14 Aug 2020 01:44:46
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:27:16
User entered 'as needed (PRN)'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:44:46
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:27:19
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 22:27:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 10:21:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	14 Aug 2020 01:45:25
answered with 'data correct as entered ' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 01:44:46
User entered 'un UNK 2000'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:27:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 01:44:46
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:27:30
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 01:44:46
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 01:44:46

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 17:59:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	30 Oct 2020 17:59:54
Data point term sent to Coder	System	30 Oct 2020 17:58:17
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 17:57:29
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:27:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 16:10:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	01 Oct 2020 16:10:57
Data point term sent to Coder	System	01 Oct 2020 16:10:09
User entered 'Ibuprofen'	Ty Henry (b) (4)	01 Oct 2020 16:10:08
	(b) (4)	

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:27:43
User entered 'No (N)'	Ty Henry (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).		02 Nov 2020 10:32:06
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' answered with 'UPDATED TERM' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:57:37
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 17:57:29
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error		30 Oct 2020 17:57:29
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM).		30 Oct 2020 12:14:23
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:27:46
User closed query 'Per ETRTR: According to AE "Symptomatic COVID-19", no medication was dosed for COVID. This medication seem to be related to COVID, so please update AE page to note medication was dosed if applicable, thanks.' (Site from CRA).		26 Oct 2020 21:53:54
Query 'Per ETRTR: According to AE "Symptomatic COVID-19", no medication was dosed for COVID. This medication seem to be related to COVID, so please update AE page to note medication was dosed if applicable, thanks.' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:11:04

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: According to AE "Symptomatic COVID-19", no medication was dosed for COVID. This medication seem to be related to COVID, so please update AE page to note medication was dosed if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	11 Oct 2020 00:37:31
User entered 'Body Aches'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:27:50
User entered '200'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:27:52
User entered 'mg (mg)'	Ty Henry (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered empty.	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:27:57
User entered 'as needed (PRN)'	Ty Henry (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered empty.	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:27:59
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered empty.	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User closed query 'Per DM CLR: Please confirm if this is for treatment of AE#9 COVID-19. Con Med start date is prior to the start date of the corresponding AE (30SEP2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 29SEP2020.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 01:26:44
' (Site from DM).		
Query 'Per DM CLR: Please confirm if this is for treatment of AE#9 COVID-19. Con Med start date is prior to the start date of the corresponding AE (30SEP2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 29SEP2020.	Sean Hansen (b) (4) (b) (4)	23 Dec 2020 23:11:00
' answered with 'Confirmed this was taken for Covid-19 symptoms and the symptoms started 9/28/20.' (Site from DM).		
User opened query 'Per DM CLR: Please confirm if this is for treatment of AE#9 COVID-19. Con Med start date is prior to the start date of the corresponding AE (30SEP2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 29SEP2020.	(b) (4), (b) (6)	03 Dec 2020 21:20:15
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:28:02
User entered '29 Sep 2020'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered '0'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:28:11
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:28:18
User entered '29 Sep 2020'	Ty Henry (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 22:28:25
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User entered empty.	System	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User entered empty.	System	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:55:43
User entered empty.	System	01 Oct 2020 16:10:08

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:28:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Oct 2020 16:13:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	22 Oct 2020 16:13:37
Data point term sent to Coder	System	22 Oct 2020 16:13:14
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:28:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:28:41
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:34
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 or provide explanation for alternate dosage. ' (Site from DM).		07 Nov 2020 18:34:49
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:34:19
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 15:34:12
User entered '1' reason for change: Data Entry Error		06 Nov 2020 15:34:12
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 or provide explanation for alternate dosage. ' (Site from DM).		06 Nov 2020 10:45:06
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:28:54
User entered '115'		22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:28:59
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:29:01
User entered 'INJECTION'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:29:06
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:29:09
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:17:34
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 22:29:13
User entered '10 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:34
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:29:17
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:29:19
User entered '10 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	26 Oct 2020 22:29:21
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User entered empty.	System	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User entered empty.	System	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:08:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:54:13
User entered empty.	System	22 Oct 2020 16:13:02

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:08:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:20
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:17:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 21:56:16

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:14

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:56
User entered '13 Oct 2020'	(b) (4), (b) (6)	02 Nov 2020 21:57:11
	(b) (4), (b) (6)	

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:56
	(b) (4), (b) (6)	
User entered 'CHEST X-RAY'	(b) (4), (b) (6)	02 Nov 2020 21:57:11

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:56
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	02 Nov 2020 21:57:11

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:08:14

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:56
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 21:57:11

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:08:14

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered '17 Nov 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:40:57

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:08:14

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Root canal'	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:40:57

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:08:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered 'Adverse Event (AE)'	Ashley Bragg (b) (4)	23 Nov 2020 21:40:57

US3332001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:08:14

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:18:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	23 Nov 2020 21:40:57

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'USA-US202-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	12 Oct 2020 15:55:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
	(b) (4), (b) (6)	
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:58
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'James'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'Peterson'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:19:08
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:21
User entered 'US'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
User entered '4'	System	23 Oct 2020 21:35:26
User entered '3'	System	19 Oct 2020 19:18:03
User entered '2'	System	14 Oct 2020 15:19:20
User entered '1'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'USA-US202-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:58
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'James'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'Peterson'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:19:08
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:21
User entered 'US'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
User entered '4'	System	23 Oct 2020 21:35:26
User entered '3'	System	19 Oct 2020 19:18:03
User entered '2'	System	14 Oct 2020 15:19:20
User entered '1'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:00
User entered '02/Oct/2020 08:46'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:08:14

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 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:00
Reviewed for Safety.		14 Oct 2020 15:19:08
User entered 'I'		02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'USA-US202-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:58
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'James'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'Peterson'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:19:08
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:21
User entered 'US'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
User entered '4'	System	23 Oct 2020 21:35:26
User entered '3'	System	19 Oct 2020 19:18:03
User entered '2'	System	14 Oct 2020 15:19:20
User entered '1'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:00
User entered '14/Oct/2020 11:19'	System	14 Oct 2020 15:19:20

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:08:14

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 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:00
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 19:17:51
User entered '1'		14 Oct 2020 15:19:20

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'USA-US202-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	12 Oct 2020 15:55:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
	(b) (4), (b) (6)	
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:58
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'James'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'Peterson'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:19:08
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:21
User entered 'US'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
User entered '4'	System	23 Oct 2020 21:35:26
User entered '3'	System	19 Oct 2020 19:18:03
User entered '2'	System	14 Oct 2020 15:19:20
User entered '1'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:08:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:00
User entered '19/Oct/2020 19:18'	System	19 Oct 2020 19:18:03

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:08:14

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 13:27:46
DataPoint Verified.	(b) (4)	10 Nov 2020 03:17:00
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:35:07
User entered '1'		19 Oct 2020 19:18:03

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:55
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'USA-US202-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:57
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:55:58
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:01
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:05
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:09
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'No (N)'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Oct 2020 15:56:11
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'James'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:46:02
User entered 'Peterson'	System	02 Oct 2020 12:45:46

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:19:08
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 15:56:21
User entered 'US'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:08:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
	(b) (4)	
User entered '4'	System	23 Oct 2020 21:35:26
User entered '3'	System	19 Oct 2020 19:18:03
User entered '2'	System	14 Oct 2020 15:19:20
User entered '1'	System	02 Oct 2020 12:46:07

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:08:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:27:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:17:00
User entered '23/Oct/2020 21:35'	System	23 Oct 2020 21:35:26

US3332001

Folder: SAE USA-US202-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:08:14

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 13:27:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 03:17:00
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 21:35:26