

US3332034 (Prod: Foothill Family Clinic)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:10:35

All time stamps listed in this document are displayed in GMT

US3332034

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 13:31:02

Generated On: 09 Jun 2021 17:10:35

[Participant ID](#)

US3332034

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

US3332034

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	31
Age Units	YEARS
Age (Derived)	31
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:15:13

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Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:15:13

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 18:15:14

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 18:15:13

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Condition	MITRAL VALVE REGURGITATION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Condition	MITRAL VALVE REPAIR
Start date (dd MMM yyyy)	17 JUN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	17 JUN 2010
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JUN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Condition	MITRAL VALVE REPAIR
Start date (dd MMM yyyy)	14 MAR 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	14 MAR 2017
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAR 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
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 18:15:13

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:15:14

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:32
Height (xxx.x)	68.5 in
Weight (xxx.x)	143.0 lb
BMI (xxx.x)	21.47162 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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 18:15:14

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 18:15:13

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Date of assessment (*dd MMM yyyy*) 10 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 18:15:14

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Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 10 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:14

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:14

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 143199

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

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 18:15:14

Generated On: 09 Jun 2021 17:10:35

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)	10 AUG 2020
Time of assessment (00:00-23:59)	12:12 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:12
Temperature (xxx.x)	99.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	13:48 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 13:48
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 13:16 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 13:16

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 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 AUG 2020
Collection time (00:00-23:59)	12:29 (24 HR)
Collection date and time (derived)	10 AUG 2020 12:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	10 AUG 2020 12:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

98.8 °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

10 AUG 2020 13:41

PC Open Date & Time

10 AUG 2020 13:36

PC Close Date & Time

10 AUG 2020 16:06

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	10 AUG 2020 17:34
PC Open Date & Time	10 AUG 2020 17:01
PC Close Date & Time	11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:02

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

12 AUG 2020 12:08

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 13:06

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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

14 AUG 2020 15:12

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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

15 AUG 2020 12:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

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

98.8 °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

16 AUG 2020 17:48

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

10 AUG 2020 13:42

PC Open Date & Time

10 AUG 2020 13:36

PC Close Date & Time

10 AUG 2020 16:06

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

10 AUG 2020 17:34

PC Open Date & Time

10 AUG 2020 17:01

PC Close Date & Time

11 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

11 AUG 2020 12:02

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

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

12 AUG 2020 12:08

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

13 AUG 2020 13:06

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 15:12

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

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

15 AUG 2020 12:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any REDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	16 AUG 2020 17:48
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 13:42
PC Open Date & Time	10 AUG 2020 13:36
PC Close Date & Time	10 AUG 2020 16:06

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 17:35
PC Open Date & Time	10 AUG 2020 17:01
PC Close Date & Time	11 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

50 of 2790

EAB) (1725)

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

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 2790

EAB) (1725)

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:08
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

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)

54 of 2790

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 13:06
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

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 ☒

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 12:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

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 2790

EAB) (1725)

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 17:48
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3332034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

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)	4 SEP 2020
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 13:55
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

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)	4 SEP 2020
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:17
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3332034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	04 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 14:46 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 14:46

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

US3332034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	4 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:20 (24 HR)
Collection date and time (derived)	4 SEP 2020 14:20

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:23	4 SEP 2020 14:23
Nasopharyngeal Swab 2	No		

US3332034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 15:18

PC Open Date & Time

04 SEP 2020 15:06

PC Close Date & Time

04 SEP 2020 17:36

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	04 SEP 2020 22:10
PC Open Date & Time	04 SEP 2020 18:31
PC Close Date & Time	05 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

99.1 °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

05 SEP 2020 13:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

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

99.2 °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

06 SEP 2020 12:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

99.5 °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

07 SEP 2020 15:48

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

08 SEP 2020 12:05

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

09 SEP 2020 14:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 13:33

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

04 SEP 2020 15:19

PC Open Date & Time

04 SEP 2020 15:06

PC Close Date & Time

04 SEP 2020 17:36

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

04 SEP 2020 22:10

PC Open Date & Time

04 SEP 2020 18:31

PC Close Date & Time

05 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

05 SEP 2020 13:16

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

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 SEP 2020 12:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

07 SEP 2020 15:48

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

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

08 SEP 2020 12:05

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

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

09 SEP 2020 14:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

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

10 SEP 2020 13:34

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 15:19
PC Open Date & Time	04 SEP 2020 15:06
PC Close Date & Time	04 SEP 2020 17:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 22:11
PC Open Date & Time	04 SEP 2020 18:31
PC Close Date & Time	05 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 13:16
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

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)

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:13
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

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EAB) (1725)

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 15:49
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

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 ☒

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 14:20
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 13:34
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3332034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:13

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	16:51 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 16:51
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3332034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	17:10 (24 HR)
Collection date and time (derived)	2 OCT 2020 17:10

US3332034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:15:14

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 11:40:51
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

17 OCT 2020 14:41:34

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

24 OCT 2020 14:03:36

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 14:00:34

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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	14 NOV 2020 07:48:30
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 19:04:06

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☒

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

27 NOV 2020 12:14:18

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 14:04:14

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☒

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 DEC 2020 20:17:58

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 12:00:15

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 22:59:32

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 06:26:27

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 21:14:22

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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	13 JAN 2021 07:54:09
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 21:31:46
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

28 JAN 2021 21:11:45

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

03 FEB 2021 21:16:03

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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	11 FEB 2021 18:59:33
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 14:29:20
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

24 FEB 2021 08:16:43

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

05 MAR 2021 12:00:24

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

10 MAR 2021 08:59:24

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

17 MAR 2021 04:06:06

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

24 MAR 2021 21:59:46

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 08:39:50
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

08 APR 2021 22:31:14

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

14 APR 2021 07:58:13

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

21 APR 2021 09:10:16

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 07:54:07

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 306

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

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

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

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

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

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

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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°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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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°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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 383

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

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

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

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

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

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

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 <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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐ 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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	23 MAR 2022 00:01
Patient Cloud Close Date & Time	27 MAR 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

Date and time of submission	
Patient Cloud Open Date & Time	17 AUG 2022 00:01
Patient Cloud Close Date & Time	21 AUG 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	24 AUG 2022 00:01
Patient Cloud Close Date & Time	28 AUG 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
---	-------------------

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3332034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:10:35

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		27 FEB 2021 21:01:51

US3332034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 00:09:58

Generated On: 09 Jun 2021 17:10:35

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) _____

US3332034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3332034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 00:09:58

Generated On: 09 Jun 2021 17:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 FEB 2021
Collection time (00:00-23:59)	16:30 (24 HR)
Collection date and time (derived)	19 FEB 2021 16:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Date of Contact	25 NOV 2020
Time of Contact	12:30
Date and Time of Contact (derived)	25 NOV 2020 12:30
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

Date	20 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

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

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

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

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

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
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EAB) (1725)		

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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"/>

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

Date	25 NOV 2020
------	-------------

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Date of Visit	25 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	25 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	27 NOV 2020
Day 5	Yes	30 NOV 2020
Day 7	Yes	02 DEC 2020
Day 9	Yes	04 DEC 2020
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3332034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 08:50:18

Generated On: 09 Jun 2021 17:10:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 12:45
Height (xxx.x)	67.0 in
Weight (xxx.x)	140.0 kg
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

US3332034

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 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 NOV 2020

US3332034

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

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

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

Folder OID	UNBLND_DECIDE
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US3332034

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:04:07

Generated On: 09 Jun 2021 17:10:35

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	11 JAN 2021
Participant randomization assignment	mRNA-1273 <input 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

US3332034

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Height	
Weight	
BMI (xxx.x)	

US3332034

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

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)	11 JAN 2021
Time of assessment (00:00-23:59)	12:01 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 12:01
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3332034

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

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)	11 JAN 2021
Time of assessment (00:00-23:59)	12:59 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 12:59
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3332034

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3332034

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

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 11 JAN 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3332034

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 JAN 2021

What was the treatment time? (00:00-23:59) 12:25 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 12:25

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

US3332034

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

11:23 (24 HR)

Collection date and time (derived)

11 JAN 2021 11:23

US3332034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	11:16
Collection Date and Time (derived)	11 JAN 2021 11:16

US3332034

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:24

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 15:58
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)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	17:18 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 17:18
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3332034

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	19 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3332034

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 16:47 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 16:47

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

US3332034

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 00:09:58

Generated On: 09 Jun 2021 17:10:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3332034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 00:09:58

Generated On: 09 Jun 2021 17:10:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3332034

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:47 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 15:47
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	108 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3332034

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3332034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 MAR 2021
Collection time (<i>00:00-23:59</i>)	15:40 (24 HR)
Collection date and time (derived)	24 MAR 2021 15:40

US3332034

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 13:31:22

Generated On: 09 Jun 2021 17:10:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

AEID

Adverse event

R EYE CONJUNCTIVITIS

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)

21 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)

22 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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

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

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

AEID	USA-US202-2021-MRNA-1273-P30 1000001
Adverse event	BILIARY DYSKINESIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 DEC 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

SUBJECT REPORTS
ABDOMINAL PAIN STARTING
APPROXIMATELY 11.1.20. PAIN
WORSENER TO THE POINT
WHERE AN ER VISIT WAS
ATTENDED 12/15/20 AND
TESTING INDICATED BILIARY
DYSKINESIA. SURGICAL
INTERVENTION WAS
SUGGESTED AND THE SUBJECT
SCHEDULED THE PROCEDURE.
SUBJECT WAS DISCHARGED
FROM THE ER THE SAME DAY.
SUBJECT RETURNED TO
HOSPITAL 12/31/20 FOR
OUTPATIENT LAPAROSCOPIC
CHOLECYSTECTOMY AND WAS
SENT HOME LATER THAT DAY.
NO COMPLICATIONS.
**PER QUERY, THE
LAPAROSCOPIC
CHOLECYSTECTOMY WAS
USED TO DIAGNOSE THE
POSTOPERATIVE TERM
BILIARY DYSKINESIA

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

AEID	
Adverse event	GASTRO ESOPHAGEAL REFLUX DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:45:39

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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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

AEID	
Adverse event	LIVER HEMANGIOMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 14:45:39

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

AEID	
Adverse event	COVID-LIKE ILLNESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 14:45:39

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

AEID	
Adverse event	TRANSIENT TACHYCARDIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 14:45:39

Generated On: 09 Jun 2021 17:10:35

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 type="radio"/> Related <input checked="" 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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication CELEXA

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication TRAZADONE

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 00:09:57

Generated On: 09 Jun 2021 17:10:35

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication MIRENA

Prophylaxis Yes ☒
No ☐

Indication PREGNANCY PROPHYLAXIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	UN NOV 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	9 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	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)		12 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)		12 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	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)	19 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 21 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication MIRENA

Prophylaxis Yes ☒
No ☐

Indication PREGNANCY PROPHYLAXIS

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

CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	9 NOV 2020	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☒
No ☐

Indication CHOLECYSTECTOMY
SURGICAL PROPHYLAXIS

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRO ESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PROPHYLAXIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	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)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication BILIARY DISKINESIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PROPHYLAXIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 Apr 2021 00:09:57

Generated On: 09 Jun 2021 17:10:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3332034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 13:31:23

Generated On: 09 Jun 2021 17:10:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 DEC 2020	LAPAROSCOPIC CHOLECYSTECTOMY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:10:35

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:10:35

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 ☐

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 16:04:07

Generated On: 09 Jun 2021 17:10:35

SAEID	USA-US202-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input 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

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 16:04:07

Generated On: 09 Jun 2021 17:10:35

SAEID	USA-US202-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input 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)	05/JAN/2021 15:50
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 16:04:07

Generated On: 09 Jun 2021 17:10:35

SAEID	USA-US202-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input 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)	15/JAN/2021 16:17
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

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 16:04:07

Generated On: 09 Jun 2021 17:10:35

SAEID	USA-US202-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input 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)	01/FEB/2021 15:17
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

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 16:04:07

Generated On: 09 Jun 2021 17:10:35

SAEID	USA-US202-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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 checked="" type="radio"/> No <input 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)	07/APR/2021 13:00
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

US3332034 (Prod: Foothill Family Clinic)

US3332034

Form: Participant Creation

Generated On: 09 Jun 2021 17:10:35

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:02
User entered 'US3332034'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:32

US3332034

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 19:32:11

US3332034

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:33

US3332034

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Clinic (Clinic)'	Sean Hansen (b) (4)	10 Aug 2020 19:32:11

US3332034

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'SCRN'	System	10 Aug 2020 19:32:11

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered (b) (6) 1989'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:34

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '31'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'YEARS'	System	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '31'	System	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Female (F)'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'I'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:35

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:32:35

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Aug 2020'	System	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2020'	System	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Amendment 2 (2)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:16

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:33

US3332034

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'I'	System	10 Aug 2020 19:33:22

US3332034

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:10:35

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:22

US3332034

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:10:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:50:40

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:51
Data point term sent to Coder	System	10 Aug 2020 19:54:27
User entered 'Mitral Valve Regurgitation'	Sean Hansen (b) (4)	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'un UNK 2005'	Sean Hansen (b) (4)	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Jan 2005'	System	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2005'	System	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	10 Aug 2020 19:54:16

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Mitral valve repair, LLT: Mitral valve repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 22:28:46
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 22:28:46
Data point term sent to Coder	System	10 Aug 2020 19:55:32
User entered 'Mitral valve repair'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '17 Jun 2010'	Sean Hansen (b) (4)	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '17 Jun 2010'	Sean Hansen (b) (4)	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Jun 2010'	System	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2010'	System	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Jun 2010'	System	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2010'	System	10 Aug 2020 19:55:28

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Mitral valve repair, LLT: Mitral valve repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Aug 2020 22:29:04
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 22:29:04
Data point term sent to Coder	System	10 Aug 2020 19:56:33
User entered 'Mitral valve repair'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '14 Mar 2017'	Sean Hansen (b) (4)	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '14 Mar 2017'	Sean Hansen (b) (4)	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Mar 2017'	System	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2017'	System	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Mar 2017'	System	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2017'	System	10 Aug 2020 19:56:09

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:04
Data point term sent to Coder	System	10 Aug 2020 19:57:35
User entered 'Anxiety'	Sean Hansen (b) (4)	10 Aug 2020 19:57:01
	(b) (4)	

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'un UNK 2015'	Sean Hansen (b) (4)	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Jan 2015'	System	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2015'	System	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	10 Aug 2020 19:57:01

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
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)	11 Aug 2020 22:29:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:29:01
Data point term sent to Coder	System	10 Aug 2020 19:59:43
User entered 'Insomnia'	Sean Hansen (b) (4)	10 Aug 2020 19:59:06
	(b) (4)	

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'un UNK 2014'	Sean Hansen (b) (4)	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Jan 2014'	System	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2014'	System	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	10 Aug 2020 19:59:06

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Oct 2020 23:40:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 23:40:08
Data point term sent to Coder	(b) (4)	
User entered 'Seasonal allergies'	System	02 Oct 2020 23:38:31
	(b) (4), (b) (6)	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'Jan 2010'	System	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '2010'	System	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:35

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	02 Oct 2020 23:37:56

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM: Please confirm if time 11:32 is AM or PM. Thank you.' (Site from DM).	(b) (4)	28 Sep 2020 06:06:02
Query 'Per CDM: Please confirm if time 11:32 is AM or PM. Thank you.' answered with '11:32 AM' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 21:59:45
User opened query 'Per CDM: Please confirm if time 11:32 is AM or PM. Thank you.' (Site from DM).	Ty Henry (b) (4)	25 Sep 2020 08:14:42
User entered '11:32'	(b) (4)	10 Aug 2020 20:07:42
	Sean Hansen (b) (4)	
	(b) (4)	

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered '10 Aug 2020 11:32'	System	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '68.5' in	(b) (4)	
	Sean Hansen (b) (4)	10 Aug 2020 20:07:42
DataPoint set to visible.	(b) (4)	
	System	10 Aug 2020 19:33:22

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '143.0' lb	(b) (4) Sean Hansen (b) (4)	10 Aug 2020 20:07:42
DataPoint set to visible.	(b) (4) System	10 Aug 2020 19:33:22

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
Amendment Manager: User entered '21.47162'	System	16 Sep 2020 23:50:22
User entered '21.5'	System	10 Aug 2020 20:07:42
DataPoint set to visible.	System	10 Aug 2020 19:33:22

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'kg/m2'	System	10 Aug 2020 20:07:42
DataPoint set to visible.	System	10 Aug 2020 19:33:22

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 06:06:05
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	25 Sep 2020 22:00:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	25 Sep 2020 22:00:08
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:14:53
User entered '99.7' F	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	(b) (4) Ty Henry (b) (4)	25 Sep 2020 22:00:08
User entered 'Oral (Oral)'	(b) (4) Sean Hansen (b) (4)	10 Aug 2020 20:07:42
	(b) (4)	

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 22:00:08
User entered '67'	Ty Henry (b) (4)	10 Aug 2020 20:07:42
	(b) (4)	

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'bpm'	System	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 22:00:08
User entered '18'	Ty Henry (b) (4)	10 Aug 2020 20:07:42
	(b) (4)	

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'breaths/min'	System	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 22:00:08
User entered '104'	Ty Henry (b) (4)	10 Aug 2020 20:07:42
	(b) (4)	

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'mmHg'	System	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 22:00:08
User entered '64'	Ty Henry (b) (4)	10 Aug 2020 20:07:42
	(b) (4)	

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered 'mmHg'	System	10 Aug 2020 20:07:42

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32

US3332034

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32

US3332034

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 20:32:48

US3332034

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 11:09:43
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 21:28:58
User entered '10 Aug 2020'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:32:48

US3332034

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 20:33:13

US3332034

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:10:35

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 20:33:13

US3332034

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:10:35

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 20:33:13

US3332034

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:10:35

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 20:33:13

US3332034

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:10:35

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 20:33:13

US3332034

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:10:35

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 20:33:13

US3332034

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:10:35

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 20:33:13

US3332034

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:10:35

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 20:33:13

US3332034

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 20:38:17

US3332034

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 20:38:17

US3332034

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Urine (URINE)'	Sean Hansen (b) (4)	10 Aug 2020 20:38:17

US3332034

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Negative (NEGATIVE)'	Sean Hansen (b) (4)	10 Aug 2020 20:38:17

US3332034

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 07:26:31
Query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	11 Sep 2020 18:06:53
User entered 'No (N)' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	11 Sep 2020 18:06:42
User opened query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 06:47:04
User closed query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 06:47:04
Query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' answered with 'Updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	09 Sep 2020 17:49:57
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	09 Sep 2020 17:49:48
User opened query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 06:35:00
User entered 'No (N)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:38:17

US3332034

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	(b) (4) Ty Henry (b) (4)	09 Sep 2020 17:49:48
User entered '10 Aug 2020'	(b) (4) Sean Hansen (b) (4)	10 Aug 2020 20:38:17
	(b) (4)	

US3332034

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	(b) (4) Ty Henry (b) (4)	09 Sep 2020 17:49:48
User entered '12:20'	(b) (4) Sean Hansen (b) (4)	10 Aug 2020 20:38:17
	(b) (4)	

US3332034

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User entered empty.	System	09 Sep 2020 17:49:48
User entered '10 Aug 2020 12:20'	System	10 Aug 2020 20:38:17

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'I'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '0'	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:25:32
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 20:39:20

US3332034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:34

US3332034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 19:33:34

US3332034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[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 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Clinic (Clinic)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:34

US3332034

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'VISIT1'	System	10 Aug 2020 19:33:34

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:48

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:22:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:22:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 18:34:48
User entered '143199' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:48

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 18:34:48

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

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 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:49

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

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 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:49

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:33:49

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:49

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 19:33:49

US3332034

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:35

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:16:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:18:05

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 21:29:00
' (Site from DM).		
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:39:20
' answered with 'Data updated.' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:39:13
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	(b) (4), (b) (6)	22 Sep 2020 19:17:12
' (Site from DM).		
User entered empty; reason for change Data Entry Error	Colby Bostock (b) (4) (b) (4)	19 Aug 2020 00:36:20
User entered '68.5' in	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 17:39:13
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	19 Aug 2020 00:36:20
User entered '143.0' lb	Colby Bostock (b) (4)	10 Aug 2020 19:34:29
	(b) (4)	

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 21:29:00
' (Site from DM).		
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:39:20
' answered with 'Data updated.' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:39:13
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	(b) (4), (b) (6)	22 Sep 2020 19:17:12
' (Site from DM).		
User entered empty; reason for change Data Entry Error	Colby Bostock (b) (4) (b) (4)	19 Aug 2020 00:36:20
User entered '68.5' in	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 17:39:13
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	19 Aug 2020 00:36:20
User entered '143.0' lb	Colby Bostock (b) (4)	10 Aug 2020 19:34:29
	(b) (4)	

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User accepted default value 'Pre-Dose (PREDOSE)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Aug 2020 18:19:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 18:19:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Aug 2020 19:34:29
User entered empty.	System	10 Aug 2020 19:34:29
	Sean Hansen (b) (4)	10 Aug 2020 19:34:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4)	17 Aug 2020 18:19:50
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:19:50
	(b) (4)	
	Sean Hansen (b) (4)	10 Aug 2020 19:34:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '12:12' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '10 Aug 2020 12:12'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '99.7' F reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Oral (Oral)' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '67' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'bpm'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '18' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'breaths/min'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '104' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '64' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 21:29:00
' (Site from DM).		
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:39:20
' answered with 'Data updated.' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:39:13
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed.	(b) (4), (b) (6)	22 Sep 2020 19:17:12
' (Site from DM).		
User entered empty; reason for change Data Entry Error	Colby Bostock (b) (4) (b) (4)	19 Aug 2020 00:36:20
User entered '68.5' in	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 17:39:13
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	19 Aug 2020 00:36:20
User entered '143.0' lb	Colby Bostock (b) (4)	10 Aug 2020 19:34:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User accepted default value 'Post-Dose (POSTDOSE)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Aug 2020 18:19:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 18:19:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Aug 2020 19:34:29
User entered empty.	System	10 Aug 2020 19:34:29
	Sean Hansen (b) (4)	10 Aug 2020 19:34:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4)	17 Aug 2020 18:19:50
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:19:50
	(b) (4)	
	Sean Hansen (b) (4)	10 Aug 2020 19:34:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM Requery : Thank you for the response,however, the treatment time on the Exposure CRF is 13:16. The Vital Signs Post Dose Time of Assessment is 13:44 which is less than 30 mins . Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 06:55:38
Query 'Per CDM Requery : Thank you for the response,however, the treatment time on the Exposure CRF is 13:16. The Vital Signs Post Dose Time of Assessment is 13:44 which is less than 30 mins . Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. ' answered with 'Data entry error. Updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	09 Sep 2020 17:51:30
User entered '13:48' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	09 Sep 2020 17:51:01
User opened query 'Per CDM Requery : Thank you for the response,however, the treatment time on the Exposure CRF is 13:16. The Vital Signs Post Dose Time of Assessment is 13:44 which is less than 30 mins . Per protocol the post dose vital signs are to be collected 30 minutes after dosing. Please clarify the post dosing time of assessment and update as needed. ' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 05:28:41
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 05:27:13
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Assessment greater than 30 minutes from Dose Time per protocol.' (Site from System).	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:21:58
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).		17 Aug 2020 18:19:50

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EAB) (1725)

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
User entered '13:44' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '10 Aug 2020 13:48'	System	09 Sep 2020 17:51:01
User entered '10 Aug 2020 13:44'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '98.8' F reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Oral (Oral)' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '87' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'bpm'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '16' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'breaths/min'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '107' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '72' reason for change: Data Entry Error	Ty Henry (b) (4)	17 Aug 2020 18:19:50
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	17 Aug 2020 18:19:50
User entered empty.	System	10 Aug 2020 19:34:29

US3332034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 00:36:10
User entered 'Yes (Y)'	Colby Bostock (b) (4)	19 Aug 2020 00:36:10
	(b) (4)	
	Sean Hansen (b) (4)	10 Aug 2020 19:34:40
	(b) (4)	

US3332034

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	(b) (4)	19 Aug 2020 00:36:10
User entered '10 Aug 2020'	Colby Bostock (b) (4)	19 Aug 2020 00:36:10
	(b) (4)	
	Sean Hansen (b) (4)	10 Aug 2020 19:34:40
	(b) (4)	

US3332034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 10:28:52
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'Updated per query.' (Site from DM).	Ty Henry (b) (4) (b) (4)	08 Sep 2020 22:36:01
User entered 'No (N)' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	08 Sep 2020 22:35:57
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 06:25:10
User entered 'Yes (Y)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:40:29

US3332034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 22:35:57
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 20:40:29

US3332034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 22:35:57
User entered 'Urine (URINE)'	Sean Hansen (b) (4)	10 Aug 2020 20:40:29

US3332034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 22:35:57
User entered 'Negative (NEGATIVE)'	Sean Hansen (b) (4)	10 Aug 2020 20:40:29

US3332034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 22:35:57
User entered 'No (N)'	Sean Hansen (b) (4)	10 Aug 2020 20:40:29

US3332034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 22:35:57
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 20:40:29

US3332034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty; reason for change Data Entry Error	Ty Henry (b) (4)	08 Sep 2020 22:35:57
User entered '12:20'	Sean Hansen (b) (4)	10 Aug 2020 20:40:29

US3332034

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered empty.	System	08 Sep 2020 22:35:57
User entered '10 Aug 2020 12:20'	System	10 Aug 2020 20:40:29

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

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 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '13:16'	Sean Hansen (b) (4)	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '10 Aug 2020 13:16'	System	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Left Arm (LEFT ARM)'	Sean Hansen (b) (4)	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'ONCE'	System	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 19:35:19

US3332034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Sean Hansen (b) (4)	10 Aug 2020 20:41:13

US3332034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 20:41:13

US3332034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '12:29'	Sean Hansen (b) (4)	10 Aug 2020 20:41:13

US3332034

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '10 Aug 2020 12:29'	System	10 Aug 2020 20:41:13

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '10 Aug 2020'	Sean Hansen (b) (4)	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4)	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '12:25'	Sean Hansen (b) (4)	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '10 Aug 2020 12:25'	System	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'No (N)'	(b) (4) Sean Hansen (b) (4) (b) (4)	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Sean Hansen (b) (4)	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered empty.	System	10 Aug 2020 20:42:25

US3332034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Sean Hansen (b) (4)	10 Aug 2020 20:42:32

US3332034

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	10 Aug 2020 20:42:32

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:41:17', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6da6f9cb-7cc9-4cc8-8262-6e266ca78023' User entered 'Yes (Y)'	System	10 Aug 2020 19:41:39
	System	10 Aug 2020 19:41:39

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:41:22', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6da6f9cb-7cc9-4cc8-8262-6e266ca78023' User entered '98.8'	System	10 Aug 2020 19:41:39
	System	10 Aug 2020 19:41:39

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:41:31', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6da6f9cb-7cc9-4cc8-8262-6e266ca78023' User entered 'No (N)'	System	10 Aug 2020 19:41:39
	System	10 Aug 2020 19:41:39

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:41:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6da6f9cb-7cc9-4cc8-8262-6e266ca78023' User entered '10 Aug 2020 13:41'	System	10 Aug 2020 19:41:39
	System	10 Aug 2020 19:41:39

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 13:36'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 16:06'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:23', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '7274f688-b374-41a4-a62a-59fe042f2b47'	System	10 Aug 2020 23:34:40
User entered 'Yes (Y)'	System	10 Aug 2020 23:34:40

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '7274f688-b374-41a4-a62a-59fe042f2b47' User entered '98.4'	System	10 Aug 2020 23:34:40
	System	10 Aug 2020 23:34:40

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:35', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '7274f688-b374-41a4-a62a-59fe042f2b47'	System	10 Aug 2020 23:34:40
User entered 'No (N)'	System	10 Aug 2020 23:34:40

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '7274f688-b374-41a4-a62a-59fe042f2b47'	System	10 Aug 2020 23:34:40
User entered '10 Aug 2020 17:34'	System	10 Aug 2020 23:34:40

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 17:01'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 2'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:14', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd9bcc682-1572-444e-b891-0bb54eb9b6cb' User entered 'Yes (Y)'	System	11 Aug 2020 18:02:49
	System	11 Aug 2020 18:02:49

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:42', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd9bcc682-1572-444e-b891-0bb54eb9b6cb' User entered '98.6'	System	11 Aug 2020 18:02:49
	System	11 Aug 2020 18:02:49

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:44', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd9bcc682-1572-444e-b891-0bb54eb9b6cb' User entered 'No (N)'	System	11 Aug 2020 18:02:49
	System	11 Aug 2020 18:02:49

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:46', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd9bcc682-1572-444e-b891-0bb54eb9b6cb' User entered '11 Aug 2020 12:02'	System	11 Aug 2020 18:02:49
	System	11 Aug 2020 18:02:49

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 3'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:07:58', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '05170dfc-251e-4da5-a9fd-6a278390ed6b' User entered 'Yes (Y)'	System	12 Aug 2020 18:08:07
	System	12 Aug 2020 18:08:07

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:02', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '05170dfc-251e-4da5-a9fd-6a278390ed6b' User entered '98.5'	System	12 Aug 2020 18:08:07
	System	12 Aug 2020 18:08:07

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:03', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '05170dfc-251e-4da5-a9fd-6a278390ed6b' User entered 'No (N)'	System	12 Aug 2020 18:08:07
	System	12 Aug 2020 18:08:07

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:05', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '05170dfc-251e-4da5-a9fd-6a278390ed6b' User entered '12 Aug 2020 12:08'	System	12 Aug 2020 18:08:07
	System	12 Aug 2020 18:08:07

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 4'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:20', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '70a5a349-0931-4875-b986-8046c2e06096'	System	13 Aug 2020 19:06:29
User entered 'Yes (Y)'	System	13 Aug 2020 19:06:29

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:23', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '70a5a349-0931-4875-b986-8046c2e06096'	System	13 Aug 2020 19:06:29
User entered '97.6'	System	13 Aug 2020 19:06:29

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:25', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '70a5a349-0931-4875-b986-8046c2e06096'	System	13 Aug 2020 19:06:29
User entered 'No (N)'	System	13 Aug 2020 19:06:29

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:27', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '70a5a349-0931-4875-b986-8046c2e06096'	System	13 Aug 2020 19:06:29
User entered '13 Aug 2020 13:06'	System	13 Aug 2020 19:06:29

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 5'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:11:34', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0180fc74-1ab1-42f9-9aab-5cbad165eaae' User entered 'Yes (Y)'	System	14 Aug 2020 21:12:19
	System	14 Aug 2020 21:12:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0180fc74-1ab1-42f9-9aab-5cbad165eaae' User entered '99.1'	System	14 Aug 2020 21:12:19
	System	14 Aug 2020 21:12:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:06', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0180fc74-1ab1-42f9-9aab-5cbad165eaae'	System	14 Aug 2020 21:12:19
User entered 'No (N)'	System	14 Aug 2020 21:12:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:15', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0180fc74-1ab1-42f9-9aab-5cbad165eaae' User entered '14 Aug 2020 15:12'	System	14 Aug 2020 21:12:19
	System	14 Aug 2020 21:12:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 6'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:18', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '32f062e2-e76c-48c3-9339-6f58e53539bb' User entered 'Yes (Y)'	System	15 Aug 2020 18:00:36
	System	15 Aug 2020 18:00:36

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:29', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '32f062e2-e76c-48c3-9339-6f58e53539bb' User entered '99.1'	System	15 Aug 2020 18:00:36
	System	15 Aug 2020 18:00:36

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:32', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '32f062e2-e76c-48c3-9339-6f58e53539bb'	System	15 Aug 2020 18:00:36
User entered 'No (N)'	System	15 Aug 2020 18:00:36

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:34', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '32f062e2-e76c-48c3-9339-6f58e53539bb' User entered '15 Aug 2020 12:00'	System	15 Aug 2020 18:00:36
	System	15 Aug 2020 18:00:36

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 7'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:17', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ff19d7b1-1813-4c51-b561-02844caad2b1' User entered 'Yes (Y)'	System	16 Aug 2020 23:48:34
	System	16 Aug 2020 23:48:34

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:23', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ff19d7b1-1813-4c51-b561-02844caad2b1' User entered '98.8'	System	16 Aug 2020 23:48:34
	System	16 Aug 2020 23:48:34

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ff19d7b1-1813-4c51-b561-02844caad2b1'	System	16 Aug 2020 23:48:34
User entered 'No (N)'	System	16 Aug 2020 23:48:34

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ff19d7b1-1813-4c51-b561-02844caad2b1' User entered '16 Aug 2020 17:48'	System	16 Aug 2020 23:48:34
	System	16 Aug 2020 23:48:34

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:41:46', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ba792acb-ff30-42bc-a1dc-a81682993aa2'	System	10 Aug 2020 19:42:07
User entered 'None (1)'	System	10 Aug 2020 19:42:07

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:41:57', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ba792acb-ff30-42bc-a1dc-a81682993aa2'	System	10 Aug 2020 19:42:07
User entered 'No (N)'	System	10 Aug 2020 19:42:07

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ba792acb-ff30-42bc-a1dc-a81682993aa2'	System	10 Aug 2020 19:42:07
User entered 'No (N)'	System	10 Aug 2020 19:42:07

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ba792acb-ff30-42bc-a1dc-a81682993aa2'	System	10 Aug 2020 19:42:07
User entered 'None (1)'	System	10 Aug 2020 19:42:07

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:06', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ba792acb-ff30-42bc-a1dc-a81682993aa2'	System	10 Aug 2020 19:42:07
User entered '10 Aug 2020 13:42'	System	10 Aug 2020 19:42:07

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 13:36'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 16:06'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:46', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '517d132e-26e5-46dc-9eeb-6a2548a9b55d' User entered 'None (1)'	System	10 Aug 2020 23:34:57
	System	10 Aug 2020 23:34:57

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:50', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '517d132e-26e5-46dc-9eeb-6a2548a9b55d' User entered 'No (N)'	System	10 Aug 2020 23:34:57
	System	10 Aug 2020 23:34:57

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:51', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '517d132e-26e5-46dc-9eeb-6a2548a9b55d' User entered 'No (N)'	System	10 Aug 2020 23:34:57
	System	10 Aug 2020 23:34:57

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:53', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '517d132e-26e5-46dc-9eeb-6a2548a9b55d' User entered 'None (1)'	System	10 Aug 2020 23:34:57
	System	10 Aug 2020 23:34:57

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:55', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '517d132e-26e5-46dc-9eeb-6a2548a9b55d' User entered '10 Aug 2020 17:34'	System	10 Aug 2020 23:34:57
	System	10 Aug 2020 23:34:57

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 17:01'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 2'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:50', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd3d3ee9-92f8-4d5c-95c7-2cf22dcc3f86'	System	11 Aug 2020 18:03:01
User entered 'None (1)'	System	11 Aug 2020 18:03:01

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:53', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd3d3ee9-92f8-4d5c-95c7-2cf22dcc3f86'	System	11 Aug 2020 18:03:01
User entered 'No (N)'	System	11 Aug 2020 18:03:01

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:55', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd3d3ee9-92f8-4d5c-95c7-2cf22dcc3f86'	System	11 Aug 2020 18:03:01
User entered 'No (N)'	System	11 Aug 2020 18:03:01

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:57', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd3d3ee9-92f8-4d5c-95c7-2cf22dcc3f86'	System	11 Aug 2020 18:03:01
User entered 'None (1)'	System	11 Aug 2020 18:03:01

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:02:59', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd3d3ee9-92f8-4d5c-95c7-2cf22dcc3f86'	System	11 Aug 2020 18:03:01
User entered '11 Aug 2020 12:02'	System	11 Aug 2020 18:03:01

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 3'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:09', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e3270e4b-e1bd-40d1-ab63-6cb0c5f6e7c5' User entered 'None (1)'	System	12 Aug 2020 18:08:18
	System	12 Aug 2020 18:08:18

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:12', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e3270e4b-e1bd-40d1-ab63-6cb0c5f6e7c5' User entered 'No (N)'	System	12 Aug 2020 18:08:18
	System	12 Aug 2020 18:08:18

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:13', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e3270e4b-e1bd-40d1-ab63-6cb0c5f6e7c5' User entered 'No (N)'	System	12 Aug 2020 18:08:18
	System	12 Aug 2020 18:08:18

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:15', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e3270e4b-e1bd-40d1-ab63-6cb0c5f6e7c5' User entered 'None (1)'	System	12 Aug 2020 18:08:18
	System	12 Aug 2020 18:08:18

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:17', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e3270e4b-e1bd-40d1-ab63-6cb0c5f6e7c5'	System	12 Aug 2020 18:08:18
User entered '12 Aug 2020 12:08'	System	12 Aug 2020 18:08:18

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 4'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '15fbf916-5d1e-41e1-9665-4f8e57f2d2f6'	System	13 Aug 2020 19:06:40
User entered 'None (1)'	System	13 Aug 2020 19:06:40

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:31', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '15fbf916-5d1e-41e1-9665-4f8e57f2d2f6' User entered 'No (N)'	System	13 Aug 2020 19:06:40
	System	13 Aug 2020 19:06:40

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:32', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '15fbf916-5d1e-41e1-9665-4f8e57f2d2f6' User entered 'No (N)'	System	13 Aug 2020 19:06:40
	System	13 Aug 2020 19:06:40

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:34', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '15fbf916-5d1e-41e1-9665-4f8e57f2d2f6'	System	13 Aug 2020 19:06:40
User entered 'None (1)'	System	13 Aug 2020 19:06:40

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:36', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '15fbf916-5d1e-41e1-9665-4f8e57f2d2f6'	System	13 Aug 2020 19:06:40
User entered '13 Aug 2020 13:06'	System	13 Aug 2020 19:06:40

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 5'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:20', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '314b0587-fe37-4039-80cc-c12a67888265'	System	14 Aug 2020 21:12:36
User entered 'None (1)'	System	14 Aug 2020 21:12:36

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:23', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '314b0587-fe37-4039-80cc-c12a67888265' User entered 'No (N)'	System	14 Aug 2020 21:12:36
	System	14 Aug 2020 21:12:36

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:25', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '314b0587-fe37-4039-80cc-c12a67888265' User entered 'No (N)'	System	14 Aug 2020 21:12:36
	System	14 Aug 2020 21:12:36

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '314b0587-fe37-4039-80cc-c12a67888265'	System	14 Aug 2020 21:12:36
User entered 'None (1)'	System	14 Aug 2020 21:12:36

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:32', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '314b0587-fe37-4039-80cc-c12a67888265'	System	14 Aug 2020 21:12:36
User entered '14 Aug 2020 15:12'	System	14 Aug 2020 21:12:36

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 6'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:37', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'caaab544-f5ba-41ae-8934-5ea4f5867529'	System	15 Aug 2020 18:00:55
User entered 'None (1)'	System	15 Aug 2020 18:00:55

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'caaab544-f5ba-41ae-8934-5ea4f5867529'	System	15 Aug 2020 18:00:55
User entered 'No (N)'	System	15 Aug 2020 18:00:55

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:44', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'caaab544-f5ba-41ae-8934-5ea4f5867529'	System	15 Aug 2020 18:00:55
User entered 'No (N)'	System	15 Aug 2020 18:00:55

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:45', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'caaab544-f5ba-41ae-8934-5ea4f5867529'	System	15 Aug 2020 18:00:55
User entered 'None (1)'	System	15 Aug 2020 18:00:55

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:00:50', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'caaab544-f5ba-41ae-8934-5ea4f5867529'	System	15 Aug 2020 18:00:55
User entered '15 Aug 2020 12:00'	System	15 Aug 2020 18:00:55

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 7'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:34', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '369b0e3b-d880-4eb3-b5a2-7ccba71d791b' User entered 'None (1)'	System	16 Aug 2020 23:48:46
	System	16 Aug 2020 23:48:46

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:36', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '369b0e3b-d880-4eb3-b5a2-7ccba71d791b' User entered 'No (N)'	System	16 Aug 2020 23:48:46
	System	16 Aug 2020 23:48:46

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '369b0e3b-d880-4eb3-b5a2-7ccba71d791b' User entered 'No (N)'	System	16 Aug 2020 23:48:46
	System	16 Aug 2020 23:48:46

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:40', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '369b0e3b-d880-4eb3-b5a2-7ccba71d791b' User entered 'None (1)'	System	16 Aug 2020 23:48:46
	System	16 Aug 2020 23:48:46

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '369b0e3b-d880-4eb3-b5a2-7ccba71d791b' User entered '16 Aug 2020 17:48'	System	16 Aug 2020 23:48:46
	System	16 Aug 2020 23:48:46

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:11', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '71b6ee5a-0a36-4567-aadb-deb913a334f6' User entered 'None (0)'	System	10 Aug 2020 19:42:33
	System	10 Aug 2020 19:42:33

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:13', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '71b6ee5a-0a36-4567-aadb-deb913a334f6' User entered 'None (0)'	System	10 Aug 2020 19:42:33
	System	10 Aug 2020 19:42:33

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:16', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '71b6ee5a-0a36-4567-aadb-deb913a334f6' User entered 'None (0)'	System	10 Aug 2020 19:42:33
	System	10 Aug 2020 19:42:33

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:18', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '71b6ee5a-0a36-4567-aadb-deb913a334f6' User entered 'None (0)'	System	10 Aug 2020 19:42:33
	System	10 Aug 2020 19:42:33

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:20', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '71b6ee5a-0a36-4567-aadb-deb913a334f6' User entered 'None (0)'	System	10 Aug 2020 19:42:33
	System	10 Aug 2020 19:42:33

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:22', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '71b6ee5a-0a36-4567-aadb-deb913a334f6' User entered 'None (0)'	System	10 Aug 2020 19:42:33
	System	10 Aug 2020 19:42:33

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:26', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '71b6ee5a-0a36-4567-aadb-deb913a334f6' User entered 'No (N)'	System	10 Aug 2020 19:42:33
	System	10 Aug 2020 19:42:33

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T13:42:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '71b6ee5a-0a36-4567-aadb-deb913a334f6' User entered '10 Aug 2020 13:42'	System	10 Aug 2020 19:42:33
	System	10 Aug 2020 19:42:33

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 13:36'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 16:06'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:58', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1b97a159-3277-435b-9b38-9df7b674bcde' User entered 'None (0)'	System	10 Aug 2020 23:35:14
	System	10 Aug 2020 23:35:14

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:34:59', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1b97a159-3277-435b-9b38-9df7b674bcde' User entered 'None (0)'	System	10 Aug 2020 23:35:14
	System	10 Aug 2020 23:35:14

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:35:01', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1b97a159-3277-435b-9b38-9df7b674bcde' User entered 'None (0)'	System	10 Aug 2020 23:35:14
	System	10 Aug 2020 23:35:14

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:35:02', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1b97a159-3277-435b-9b38-9df7b674bcde' User entered 'None (0)'	System	10 Aug 2020 23:35:14
	System	10 Aug 2020 23:35:14

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:35:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1b97a159-3277-435b-9b38-9df7b674bcde' User entered 'None (0)'	System	10 Aug 2020 23:35:14
	System	10 Aug 2020 23:35:14

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:35:05', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1b97a159-3277-435b-9b38-9df7b674bcde' User entered 'None (0)'	System	10 Aug 2020 23:35:14
	System	10 Aug 2020 23:35:14

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:35:09', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1b97a159-3277-435b-9b38-9df7b674bcde' User entered 'No (N)'	System	10 Aug 2020 23:35:14
	System	10 Aug 2020 23:35:14

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-10T17:35:11', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1b97a159-3277-435b-9b38-9df7b674bcde' User entered '10 Aug 2020 17:35'	System	10 Aug 2020 23:35:14
	System	10 Aug 2020 23:35:14

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Aug 2020 17:01'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 2'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:03:02', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3a32612-ce90-4547-84d4-2a830d6a1097' User entered 'None (0)'	System	11 Aug 2020 18:03:21
	System	11 Aug 2020 18:03:21

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:03:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3a32612-ce90-4547-84d4-2a830d6a1097' User entered 'None (0)'	System	11 Aug 2020 18:03:21
	System	11 Aug 2020 18:03:21

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:03:07', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3a32612-ce90-4547-84d4-2a830d6a1097' User entered 'None (0)'	System	11 Aug 2020 18:03:21
	System	11 Aug 2020 18:03:21

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:03:08', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3a32612-ce90-4547-84d4-2a830d6a1097' User entered 'None (0)'	System	11 Aug 2020 18:03:21
	System	11 Aug 2020 18:03:21

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:03:10', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3a32612-ce90-4547-84d4-2a830d6a1097' User entered 'None (0)'	System	11 Aug 2020 18:03:21
	System	11 Aug 2020 18:03:21

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:03:12', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3a32612-ce90-4547-84d4-2a830d6a1097' User entered 'None (0)'	System	11 Aug 2020 18:03:21
	System	11 Aug 2020 18:03:21

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:03:16', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3a32612-ce90-4547-84d4-2a830d6a1097'	System	11 Aug 2020 18:03:21
User entered 'No (N)'	System	11 Aug 2020 18:03:21

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-11T12:03:17', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3a32612-ce90-4547-84d4-2a830d6a1097'	System	11 Aug 2020 18:03:21
User entered '11 Aug 2020 12:03'	System	11 Aug 2020 18:03:21

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 3'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:31', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '327dd0cc-aaaa-4988-a34a-f44e843eab62'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:33', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '327dd0cc-acaa-4988-a34a-f44e843eab62' User entered 'None (0)'	System	12 Aug 2020 18:08:52
	System	12 Aug 2020 18:08:52

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:35', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '327dd0cc-acaa-4988-a34a-f44e843eab62'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:37', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '327dd0cc-aaaa-4988-a34a-f44e843eab62' User entered 'None (0)'	System	12 Aug 2020 18:08:52
	System	12 Aug 2020 18:08:52

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:42', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '327dd0cc-acaa-4988-a34a-f44e843eab62'	System	12 Aug 2020 18:08:52
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	12 Aug 2020 18:08:52

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:44', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '327dd0cc-aaaa-4988-a34a-f44e843eab62'	System	12 Aug 2020 18:08:52
User entered 'None (0)'	System	12 Aug 2020 18:08:52

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:47', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '327dd0cc-acaa-4988-a34a-f44e843eab62'	System	12 Aug 2020 18:08:52
User entered 'No (N)'	System	12 Aug 2020 18:08:52

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-12T12:08:49', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '327dd0cc-aaaa-4988-a34a-f44e843eab62'	System	12 Aug 2020 18:08:52
User entered '12 Aug 2020 12:08'	System	12 Aug 2020 18:08:52

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 4'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'faa3ae23-1da2-406b-ab84-a09da4d0f53b' User entered 'None (0)'	System	13 Aug 2020 19:06:51
	System	13 Aug 2020 19:06:51

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:39', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'faa3ae23-1da2-406b-ab84-a09da4d0f53b' User entered 'None (0)'	System	13 Aug 2020 19:06:51
	System	13 Aug 2020 19:06:51

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:40', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'faa3ae23-1da2-406b-ab84-a09da4d0f53b' User entered 'None (0)'	System	13 Aug 2020 19:06:51
	System	13 Aug 2020 19:06:51

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:41', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'faa3ae23-1da2-406b-ab84-a09da4d0f53b' User entered 'None (0)'	System	13 Aug 2020 19:06:51
	System	13 Aug 2020 19:06:51

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:42', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'faa3ae23-1da2-406b-ab84-a09da4d0f53b' User entered 'None (0)'	System	13 Aug 2020 19:06:51
	System	13 Aug 2020 19:06:51

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'faa3ae23-1da2-406b-ab84-a09da4d0f53b' User entered 'None (0)'	System	13 Aug 2020 19:06:51
	System	13 Aug 2020 19:06:51

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:47', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'faa3ae23-1da2-406b-ab84-a09da4d0f53b'	System	13 Aug 2020 19:06:51
User entered 'No (N)'	System	13 Aug 2020 19:06:51

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-13T13:06:49', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'faa3ae23-1da2-406b-ab84-a09da4d0f53b' User entered '13 Aug 2020 13:06'	System	13 Aug 2020 19:06:51
	System	13 Aug 2020 19:06:51

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 5'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:36', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6f75b9f8-54d5-4cba-9d85-27743c6c16a6' User entered 'None (0)'	System	14 Aug 2020 21:12:47
	System	14 Aug 2020 21:12:47

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:37', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6f75b9f8-54d5-4cba-9d85-27743c6c16a6' User entered 'None (0)'	System	14 Aug 2020 21:12:47
	System	14 Aug 2020 21:12:47

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6f75b9f8-54d5-4cba-9d85-27743c6c16a6' User entered 'None (0)'	System	14 Aug 2020 21:12:47
	System	14 Aug 2020 21:12:47

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:39', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6f75b9f8-54d5-4cba-9d85-27743c6c16a6' User entered 'None (0)'	System	14 Aug 2020 21:12:47
	System	14 Aug 2020 21:12:47

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:40', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6f75b9f8-54d5-4cba-9d85-27743c6c16a6' User entered 'None (0)'	System	14 Aug 2020 21:12:47
	System	14 Aug 2020 21:12:47

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:41', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6f75b9f8-54d5-4cba-9d85-27743c6c16a6' User entered 'None (0)'	System	14 Aug 2020 21:12:47
	System	14 Aug 2020 21:12:47

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:42', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6f75b9f8-54d5-4cba-9d85-27743c6c16a6' User entered 'No (N)'	System	14 Aug 2020 21:12:47
	System	14 Aug 2020 21:12:47

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-14T15:12:44', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6f75b9f8-54d5-4cba-9d85-27743c6c16a6' User entered '14 Aug 2020 15:12'	System	14 Aug 2020 21:12:47
	System	14 Aug 2020 21:12:47

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 6'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:01:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '8711a0a3-373f-405c-bb18-2155d64983f1' User entered 'None (0)'	System	15 Aug 2020 18:01:12
	System	15 Aug 2020 18:01:12

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:01:01', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '8711a0a3-373f-405c-bb18-2155d64983f1' User entered 'None (0)'	System	15 Aug 2020 18:01:12
	System	15 Aug 2020 18:01:12

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:01:03', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '8711a0a3-373f-405c-bb18-2155d64983f1' User entered 'None (0)'	System	15 Aug 2020 18:01:12
	System	15 Aug 2020 18:01:12

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:01:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '8711a0a3-373f-405c-bb18-2155d64983f1' User entered 'None (0)'	System	15 Aug 2020 18:01:12
	System	15 Aug 2020 18:01:12

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:01:05', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '8711a0a3-373f-405c-bb18-2155d64983f1' User entered 'None (0)'	System	15 Aug 2020 18:01:12
	System	15 Aug 2020 18:01:12

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:01:06', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '8711a0a3-373f-405c-bb18-2155d64983f1' User entered 'None (0)'	System	15 Aug 2020 18:01:12
	System	15 Aug 2020 18:01:12

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:01:08', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '8711a0a3-373f-405c-bb18-2155d64983f1' User entered 'No (N)'	System	15 Aug 2020 18:01:12
	System	15 Aug 2020 18:01:12

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-15T12:01:11', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '8711a0a3-373f-405c-bb18-2155d64983f1' User entered '15 Aug 2020 12:01'	System	15 Aug 2020 18:01:12
	System	15 Aug 2020 18:01:12

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 7'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:46', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84b268d0-c753-42e8-81c8-ab66ad5ef38a' User entered 'None (0)'	System	16 Aug 2020 23:49:01
	System	16 Aug 2020 23:49:01

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:48', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84b268d0-c753-42e8-81c8-ab66ad5ef38a' User entered 'None (0)'	System	16 Aug 2020 23:49:01
	System	16 Aug 2020 23:49:01

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:49', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84b268d0-c753-42e8-81c8-ab66ad5ef38a' User entered 'None (0)'	System	16 Aug 2020 23:49:01
	System	16 Aug 2020 23:49:01

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:51', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84b268d0-c753-42e8-81c8-ab66ad5ef38a' User entered 'None (0)'	System	16 Aug 2020 23:49:01
	System	16 Aug 2020 23:49:01

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:52', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84b268d0-c753-42e8-81c8-ab66ad5ef38a' User entered 'None (0)'	System	16 Aug 2020 23:49:01
	System	16 Aug 2020 23:49:01

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:53', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84b268d0-c753-42e8-81c8-ab66ad5ef38a' User entered 'None (0)'	System	16 Aug 2020 23:49:01
	System	16 Aug 2020 23:49:01

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:56', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84b268d0-c753-42e8-81c8-ab66ad5ef38a' User entered 'No (N)'	System	16 Aug 2020 23:49:01
	System	16 Aug 2020 23:49:01

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-08-16T17:48:58', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84b268d0-c753-42e8-81c8-ab66ad5ef38a' User entered '16 Aug 2020 17:48'	System	16 Aug 2020 23:49:01
	System	16 Aug 2020 23:49:01

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 19:35:19

US3332034

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	19 Aug 2020 00:35:52

US3332034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '18 Aug 2020'	Colby Bostock (b) (4)	19 Aug 2020 00:35:52

US3332034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colby Bostock (b) (4) (b) (4)	19 Aug 2020 00:35:52

US3332034

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	19 Aug 2020 00:35:52

US3332034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	19 Aug 2020 00:35:43

US3332034

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	19 Aug 2020 00:35:43

US3332034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 16:43:32

US3332034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 16:43:32

US3332034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 16:43:32

US3332034

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 16:43:32

US3332034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 16:43:38

US3332034

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	24 Aug 2020 16:43:38

US3332034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:08:27

US3332034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:08:27

US3332034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:08:27

US3332034

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:08:27

US3332034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 01:08:32

US3332034

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	01 Sep 2020 01:08:32

US3332034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	04 Sep 2020 21:28:58

US3332034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'visit within window' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 08:03:54
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	Colby Bostock (b) (4)	04 Sep 2020 21:31:01
User entered '4 Sep 2020'	(b) (4)	
	System	04 Sep 2020 21:28:58
	Colby Bostock (b) (4)	04 Sep 2020 21:28:58
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[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 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Clinic (Clinic)'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:28:58

US3332034

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'VISIT2'	System	04 Sep 2020 21:28:58

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User accepted default value 'Pre-Dose (PREDOSE)'	Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '4 Sep 2020'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '13:55'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '4 Sep 2020 13:55'	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '98.5' F	Colby Bostock (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Oral (Oral)'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:52:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 17:52:45
User entered '95' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Sep 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'bpm'	System	09 Sep 2020 17:52:45
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:52:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 17:52:45
User entered '16' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Sep 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'breaths/min'	System	09 Sep 2020 17:52:45
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:52:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 17:52:45
User entered '110' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Sep 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	09 Sep 2020 17:52:45
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:52:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 17:52:45
User entered '74' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Sep 2020 17:52:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	09 Sep 2020 17:52:45
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User accepted default value 'Post-Dose (POSTDOSE)'	Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '4 Sep 2020'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:32:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	04 Sep 2020 21:32:03
User entered '15:17' reason for change: Data Entry Error	Colby Bostock (b) (4)	04 Sep 2020 21:32:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	System	04 Sep 2020 21:31:53
	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '4 Sep 2020 15:17'	System	04 Sep 2020 21:32:03
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '98.4' F	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Oral (Oral)'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:53:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 17:53:14
User entered '86' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Sep 2020 17:53:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'bpm'	System	09 Sep 2020 17:53:14
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:53:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 17:53:14
User entered '20' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Sep 2020 17:53:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'breaths/min'	System	09 Sep 2020 17:53:14
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:53:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 17:53:14
User entered '98' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Sep 2020 17:53:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	09 Sep 2020 17:53:14
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 17:53:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 17:53:14
User entered '64' reason for change: Data Entry Error	Ty Henry (b) (4)	09 Sep 2020 17:53:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:31:53
User entered empty.	Colby Bostock (b) (4)	04 Sep 2020 21:31:53
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	09 Sep 2020 17:53:14
User entered empty.	System	04 Sep 2020 21:31:53

US3332034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	04 Sep 2020 21:32:12

US3332034

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '4 Sep 2020'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:32:12

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Ty Henry (b) (4)	09 Sep 2020 17:54:17

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '04 Sep 2020'	Ty Henry (b) (4)	09 Sep 2020 17:54:17

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Urine (URINE)'	Ty Henry (b) (4)	09 Sep 2020 17:54:17

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Negative (NEGATIVE)'	Ty Henry (b) (4)	09 Sep 2020 17:54:17

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 07:02:11
Query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' answered with 'Data updated.' (Site from DM).	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:40:02
User entered 'No (N)' reason for change: Data Entry Error	Ty Henry (b) (4) (b) (4)	23 Sep 2020 17:39:54
User opened query 'Per CDM: Please consider answering "Was FSH sample collected?" as Yes or No. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:55:53
User entered empty.	Ty Henry (b) (4) (b) (4)	09 Sep 2020 17:54:17

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:54:17

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Ty Henry (b) (4)	09 Sep 2020 17:54:17

US3332034

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered empty.	System	09 Sep 2020 17:54:17

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

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 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '14:46'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '4 Sep 2020 14:46'	System	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'ONCE'	System	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 21:14:04

US3332034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	04 Sep 2020 21:33:31

US3332034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '4 Sep 2020'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:33:31

US3332034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '14:20'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:33:31

US3332034

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '4 Sep 2020 14:20'	System	04 Sep 2020 21:33:31

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '4 Sep 2020'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:35:25

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:35:25

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:35:25

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '14:23'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:35:25

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '4 Sep 2020 14:23'	System	04 Sep 2020 21:35:25

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:35:25

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 21:35:31
User entered 'No (N)' reason for change: Data Entry Error	Colby Bostock (b) (4)	04 Sep 2020 21:35:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	04 Sep 2020 21:35:25
	Colby Bostock (b) (4)	04 Sep 2020 21:35:25
	(b) (4)	

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:35:25

US3332034

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered empty.	System	04 Sep 2020 21:35:25

US3332034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	04 Sep 2020 21:35:40

US3332034

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	04 Sep 2020 21:35:40

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:18:09', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '645c8307-117c-4839-8df7-d3b2e8d12253' User entered 'Yes (Y)'	System	04 Sep 2020 21:18:26
	System	04 Sep 2020 21:18:26

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:18:17', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '645c8307-117c-4839-8df7-d3b2e8d12253' User entered '98.4'	System	04 Sep 2020 21:18:26
	System	04 Sep 2020 21:18:26

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:18:20', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '645c8307-117c-4839-8df7-d3b2e8d12253' User entered 'No (N)'	System	04 Sep 2020 21:18:26
	System	04 Sep 2020 21:18:26

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:18:23', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '645c8307-117c-4839-8df7-d3b2e8d12253' User entered '04 Sep 2020 15:18'	System	04 Sep 2020 21:18:26
	System	04 Sep 2020 21:18:26

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '04 Sep 2020 15:06'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '04 Sep 2020 17:36'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'bd84bd09-476a-47e5-8ed1-e79e8d78c319' User entered 'Yes (Y)'	System	05 Sep 2020 04:10:43
	System	05 Sep 2020 04:10:43

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:32', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'bd84bd09-476a-47e5-8ed1-e79e8d78c319' User entered '98.7'	System	05 Sep 2020 04:10:43
	System	05 Sep 2020 04:10:43

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:36', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'bd84bd09-476a-47e5-8ed1-e79e8d78c319' User entered 'No (N)'	System	05 Sep 2020 04:10:43
	System	05 Sep 2020 04:10:43

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:41', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'bd84bd09-476a-47e5-8ed1-e79e8d78c319' User entered '04 Sep 2020 22:10'	System	05 Sep 2020 04:10:43
	System	05 Sep 2020 04:10:43

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '04 Sep 2020 18:31'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 2'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:15:54', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3adaca1-d9cd-46f1-ab5b-8c545e5ca420' User entered 'Yes (Y)'	System	05 Sep 2020 19:16:08
	System	05 Sep 2020 19:16:08

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:15:59', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3adaca1-d9cd-46f1-ab5b-8c545e5ca420' User entered '99.1'	System	05 Sep 2020 19:16:08
	System	05 Sep 2020 19:16:08

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:02', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3adaca1-d9cd-46f1-ab5b-8c545e5ca420' User entered 'No (N)'	System	05 Sep 2020 19:16:08
	System	05 Sep 2020 19:16:08

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd3adaca1-d9cd-46f1-ab5b-8c545e5ca420' User entered '05 Sep 2020 13:16'	System	05 Sep 2020 19:16:08
	System	05 Sep 2020 19:16:08

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 3'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:05', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '150c5569-ada3-4953-9ee3-838f69130893' User entered 'Yes (Y)'	System	06 Sep 2020 18:13:18
	System	06 Sep 2020 18:13:18

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:08', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '150c5569-ada3-4953-9ee3-838f69130893' User entered '99.2'	System	06 Sep 2020 18:13:18
	System	06 Sep 2020 18:13:18

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:10', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '150c5569-ada3-4953-9ee3-838f69130893'	System	06 Sep 2020 18:13:18
User entered 'No (N)'	System	06 Sep 2020 18:13:18

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:14', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '150c5569-ada3-4953-9ee3-838f69130893'	System	06 Sep 2020 18:13:18
User entered '06 Sep 2020 12:13'	System	06 Sep 2020 18:13:18

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 4'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '10754771-0d1e-4af4-942c-536fdb514bf' User entered 'Yes (Y)'	System	07 Sep 2020 21:48:50
	System	07 Sep 2020 21:48:50

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '10754771-0d1e-4af4-942c-536fdb514bf' User entered '99.5'	System	07 Sep 2020 21:48:50
	System	07 Sep 2020 21:48:50

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:45', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '10754771-0d1e-4af4-942c-536fdb514bf' User entered 'No (N)'	System	07 Sep 2020 21:48:50
	System	07 Sep 2020 21:48:50

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:47', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '10754771-0d1e-4af4-942c-536fdb514bf' User entered '07 Sep 2020 15:48'	System	07 Sep 2020 21:48:50
	System	07 Sep 2020 21:48:50

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 5'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:15', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd71b19f0-145e-4b30-9abb-9510d0ec00c7' User entered 'Yes (Y)'	System	08 Sep 2020 18:05:39
	System	08 Sep 2020 18:05:39

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd71b19f0-145e-4b30-9abb-9510d0ec00c7' User entered '98.6'	System	08 Sep 2020 18:05:39
	System	08 Sep 2020 18:05:39

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd71b19f0-145e-4b30-9abb-9510d0ec00c7'	System	08 Sep 2020 18:05:39
User entered 'No (N)'	System	08 Sep 2020 18:05:39

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:33', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'd71b19f0-145e-4b30-9abb-9510d0ec00c7' User entered '08 Sep 2020 12:05'	System	08 Sep 2020 18:05:39
	System	08 Sep 2020 18:05:39

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 6'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:19:49', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9ad5c159-86e5-40c9-b693-947da3719f7d' User entered 'Yes (Y)'	System	09 Sep 2020 20:20:20
	System	09 Sep 2020 20:20:20

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:14', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9ad5c159-86e5-40c9-b693-947da3719f7d' User entered '98.9'	System	09 Sep 2020 20:20:20
	System	09 Sep 2020 20:20:20

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:16', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9ad5c159-86e5-40c9-b693-947da3719f7d' User entered 'No (N)'	System	09 Sep 2020 20:20:20
	System	09 Sep 2020 20:20:20

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:18', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9ad5c159-86e5-40c9-b693-947da3719f7d' User entered '09 Sep 2020 14:20'	System	09 Sep 2020 20:20:20
	System	09 Sep 2020 20:20:20

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 7'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:33:49', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1841a9b6-9475-4ea1-b7b0-f04803c4dae9' User entered 'Yes (Y)'	System	10 Sep 2020 19:34:03
	System	10 Sep 2020 19:34:03

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:33:55', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1841a9b6-9475-4ea1-b7b0-f04803c4dae9' User entered '98.7'	System	10 Sep 2020 19:34:03
	System	10 Sep 2020 19:34:03

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:33:57', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1841a9b6-9475-4ea1-b7b0-f04803c4dae9' User entered 'No (N)'	System	10 Sep 2020 19:34:03
	System	10 Sep 2020 19:34:03

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:33:59', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1841a9b6-9475-4ea1-b7b0-f04803c4dae9' User entered '10 Sep 2020 13:33'	System	10 Sep 2020 19:34:03
	System	10 Sep 2020 19:34:03

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:18:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0d499559-2732-481a-9395-edb10b6bd2c0'	System	04 Sep 2020 21:19:12
User entered 'None (1)'	System	04 Sep 2020 21:19:12

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:18:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0d499559-2732-481a-9395-edb10b6bd2c0' User entered 'No (N)'	System	04 Sep 2020 21:19:12
	System	04 Sep 2020 21:19:12

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:18:48', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0d499559-2732-481a-9395-edb10b6bd2c0' User entered 'No (N)'	System	04 Sep 2020 21:19:12
	System	04 Sep 2020 21:19:12

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:06', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0d499559-2732-481a-9395-edb10b6bd2c0'	System	04 Sep 2020 21:19:12
User entered 'None (1)'	System	04 Sep 2020 21:19:12

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:10', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '0d499559-2732-481a-9395-edb10b6bd2c0' User entered '04 Sep 2020 15:19'	System	04 Sep 2020 21:19:12
	System	04 Sep 2020 21:19:12

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '04 Sep 2020 15:06'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '04 Sep 2020 17:36'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:45', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'df9b6a96-65e7-4667-9955-f25b997bc4b5' User entered 'None (1)'	System	05 Sep 2020 04:10:55
	System	05 Sep 2020 04:10:55

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:47', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'df9b6a96-65e7-4667-9955-f25b997bc4b5' User entered 'No (N)'	System	05 Sep 2020 04:10:55
	System	05 Sep 2020 04:10:55

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:48', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'df9b6a96-65e7-4667-9955-f25b997bc4b5' User entered 'No (N)'	System	05 Sep 2020 04:10:55
	System	05 Sep 2020 04:10:55

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:49', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'df9b6a96-65e7-4667-9955-f25b997bc4b5'	System	05 Sep 2020 04:10:55
User entered 'None (1)'	System	05 Sep 2020 04:10:55

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:52', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'df9b6a96-65e7-4667-9955-f25b997bc4b5'	System	05 Sep 2020 04:10:55
User entered '04 Sep 2020 22:10'	System	05 Sep 2020 04:10:55

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '04 Sep 2020 18:31'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 2'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:08', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e1fc09fc-535a-4e0d-af22-453fc6e25953'	System	05 Sep 2020 19:16:27
User entered 'None (1)'	System	05 Sep 2020 19:16:27

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:17', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e1fc09fc-535a-4e0d-af22-453fc6e25953'	System	05 Sep 2020 19:16:27
User entered 'No (N)'	System	05 Sep 2020 19:16:27

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:21', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e1fc09fc-535a-4e0d-af22-453fc6e25953'	System	05 Sep 2020 19:16:27
User entered 'No (N)'	System	05 Sep 2020 19:16:27

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:23', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e1fc09fc-535a-4e0d-af22-453fc6e25953'	System	05 Sep 2020 19:16:27
User entered 'None (1)'	System	05 Sep 2020 19:16:27

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:25', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e1fc09fc-535a-4e0d-af22-453fc6e25953'	System	05 Sep 2020 19:16:27
User entered '05 Sep 2020 13:16'	System	05 Sep 2020 19:16:27

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 3'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:21', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'fcd2f3e9-0f75-4ae1-8122-99067b810bf8' User entered 'None (1)'	System	06 Sep 2020 18:13:29
	System	06 Sep 2020 18:13:29

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:23', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'fcd2f3e9-0f75-4ae1-8122-99067b810bf8' User entered 'No (N)'	System	06 Sep 2020 18:13:29
	System	06 Sep 2020 18:13:29

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:24', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'fcd2f3e9-0f75-4ae1-8122-99067b810bf8' User entered 'No (N)'	System	06 Sep 2020 18:13:29
	System	06 Sep 2020 18:13:29

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:26', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'fcd2f3e9-0f75-4ae1-8122-99067b810bf8' User entered 'None (1)'	System	06 Sep 2020 18:13:29
	System	06 Sep 2020 18:13:29

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:27', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'fcd2f3e9-0f75-4ae1-8122-99067b810bf8' User entered '06 Sep 2020 12:13'	System	06 Sep 2020 18:13:29
	System	06 Sep 2020 18:13:29

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 4'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:51', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '88e051ad-8340-46cb-b472-041092482e59'	System	07 Sep 2020 21:49:00
User entered 'None (1)'	System	07 Sep 2020 21:49:00

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:52', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '88e051ad-8340-46cb-b472-041092482e59'	System	07 Sep 2020 21:49:00
User entered 'No (N)'	System	07 Sep 2020 21:49:00

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:53', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '88e051ad-8340-46cb-b472-041092482e59' User entered 'No (N)'	System	07 Sep 2020 21:49:00
	System	07 Sep 2020 21:49:00

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:54', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '88e051ad-8340-46cb-b472-041092482e59'	System	07 Sep 2020 21:49:00
User entered 'None (1)'	System	07 Sep 2020 21:49:00

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:48:56', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '88e051ad-8340-46cb-b472-041092482e59' User entered '07 Sep 2020 15:48'	System	07 Sep 2020 21:49:00
	System	07 Sep 2020 21:49:00

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 5'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:35', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c3044c5e-9369-4ea9-a555-a141d044a33d' User entered 'None (1)'	System	08 Sep 2020 18:05:44
	System	08 Sep 2020 18:05:44

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:37', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c3044c5e-9369-4ea9-a555-a141d044a33d' User entered 'No (N)'	System	08 Sep 2020 18:05:44
	System	08 Sep 2020 18:05:44

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c3044c5e-9369-4ea9-a555-a141d044a33d' User entered 'No (N)'	System	08 Sep 2020 18:05:44
	System	08 Sep 2020 18:05:44

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:39', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c3044c5e-9369-4ea9-a555-a141d044a33d' User entered 'None (1)'	System	08 Sep 2020 18:05:44
	System	08 Sep 2020 18:05:44

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:41', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c3044c5e-9369-4ea9-a555-a141d044a33d' User entered '08 Sep 2020 12:05'	System	08 Sep 2020 18:05:44
	System	08 Sep 2020 18:05:44

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 6'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:25', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '789623e4-cfb7-4296-86e5-a3fe7bafcb33'	System	09 Sep 2020 20:20:35
User entered 'None (1)'	System	09 Sep 2020 20:20:35

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:26', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '789623e4-cfb7-4296-86e5-a3fe7bafcb33' User entered 'No (N)'	System	09 Sep 2020 20:20:35
	System	09 Sep 2020 20:20:35

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:27', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '789623e4-cfb7-4296-86e5-a3fe7bafcb33' User entered 'No (N)'	System	09 Sep 2020 20:20:35
	System	09 Sep 2020 20:20:35

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '789623e4-cfb7-4296-86e5-a3fe7bafcb33'	System	09 Sep 2020 20:20:35
User entered 'None (1)'	System	09 Sep 2020 20:20:35

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '789623e4-cfb7-4296-86e5-a3fe7bafcb33' User entered '09 Sep 2020 14:20'	System	09 Sep 2020 20:20:35
	System	09 Sep 2020 20:20:35

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 7'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:03', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '39dbefd8-1f77-47b0-a3b9-f452b3867a96' User entered 'None (1)'	System	10 Sep 2020 19:34:09
	System	10 Sep 2020 19:34:09

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '39dbefd8-1f77-47b0-a3b9-f452b3867a96' User entered 'No (N)'	System	10 Sep 2020 19:34:09
	System	10 Sep 2020 19:34:09

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:05', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '39dbefd8-1f77-47b0-a3b9-f452b3867a96' User entered 'No (N)'	System	10 Sep 2020 19:34:09
	System	10 Sep 2020 19:34:09

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:06', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '39dbefd8-1f77-47b0-a3b9-f452b3867a96' User entered 'None (1)'	System	10 Sep 2020 19:34:09
	System	10 Sep 2020 19:34:09

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:07', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '39dbefd8-1f77-47b0-a3b9-f452b3867a96' User entered '10 Sep 2020 13:34'	System	10 Sep 2020 19:34:09
	System	10 Sep 2020 19:34:09

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:19', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '51954e0d-4ee4-4d47-8c3d-5f8a22f00aec' User entered 'None (0)'	System	04 Sep 2020 21:19:36
	System	04 Sep 2020 21:19:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:21', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '51954e0d-4ee4-4d47-8c3d-5f8a22f00aec' User entered 'None (0)'	System	04 Sep 2020 21:19:36
	System	04 Sep 2020 21:19:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:22', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '51954e0d-4ee4-4d47-8c3d-5f8a22f00aec' User entered 'None (0)'	System	04 Sep 2020 21:19:36
	System	04 Sep 2020 21:19:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:23', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '51954e0d-4ee4-4d47-8c3d-5f8a22f00aec' User entered 'None (0)'	System	04 Sep 2020 21:19:36
	System	04 Sep 2020 21:19:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:25', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '51954e0d-4ee4-4d47-8c3d-5f8a22f00aec' User entered 'None (0)'	System	04 Sep 2020 21:19:36
	System	04 Sep 2020 21:19:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:26', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '51954e0d-4ee4-4d47-8c3d-5f8a22f00aec' User entered 'None (0)'	System	04 Sep 2020 21:19:36
	System	04 Sep 2020 21:19:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:32', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '51954e0d-4ee4-4d47-8c3d-5f8a22f00aec' User entered 'No (N)'	System	04 Sep 2020 21:19:36
	System	04 Sep 2020 21:19:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T15:19:34', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '51954e0d-4ee4-4d47-8c3d-5f8a22f00aec' User entered '04 Sep 2020 15:19'	System	04 Sep 2020 21:19:36
	System	04 Sep 2020 21:19:36

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '04 Sep 2020 15:06'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '04 Sep 2020 17:36'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:55', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'eaf940c4-fa97-4e6d-8fc7-3251d1f256f7' User entered 'None (0)'	System	05 Sep 2020 04:11:09
	System	05 Sep 2020 04:11:09

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:56', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'eaf940c4-fa97-4e6d-8fc7-3251d1f256f7' User entered 'None (0)'	System	05 Sep 2020 04:11:09
	System	05 Sep 2020 04:11:09

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:57', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'eaf940c4-fa97-4e6d-8fc7-3251d1f256f7' User entered 'None (0)'	System	05 Sep 2020 04:11:09
	System	05 Sep 2020 04:11:09

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:58', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'eaf940c4-fa97-4e6d-8fc7-3251d1f256f7' User entered 'None (0)'	System	05 Sep 2020 04:11:09
	System	05 Sep 2020 04:11:09

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:10:59', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'eaf940c4-fa97-4e6d-8fc7-3251d1f256f7' User entered 'None (0)'	System	05 Sep 2020 04:11:09
	System	05 Sep 2020 04:11:09

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:11:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'eaf940c4-fa97-4e6d-8fc7-3251d1f256f7' User entered 'None (0)'	System	05 Sep 2020 04:11:09
	System	05 Sep 2020 04:11:09

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:11:03', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'eaf940c4-fa97-4e6d-8fc7-3251d1f256f7'	System	05 Sep 2020 04:11:09
User entered 'No (N)'	System	05 Sep 2020 04:11:09

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-04T22:11:05', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'eaf940c4-fa97-4e6d-8fc7-3251d1f256f7'	System	05 Sep 2020 04:11:09
User entered '04 Sep 2020 22:11'	System	05 Sep 2020 04:11:09

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '04 Sep 2020 18:31'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 2'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f90db840-cbf4-4566-8312-98be83e51342' User entered 'None (0)'	System	05 Sep 2020 19:16:47
	System	05 Sep 2020 19:16:47

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:33', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f90db840-cbf4-4566-8312-98be83e51342'	System	05 Sep 2020 19:16:47
User entered 'No interference with activity (1)'	System	05 Sep 2020 19:16:47

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:35', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f90db840-cbf4-4566-8312-98be83e51342' User entered 'None (0)'	System	05 Sep 2020 19:16:47
	System	05 Sep 2020 19:16:47

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:36', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f90db840-cbf4-4566-8312-98be83e51342' User entered 'None (0)'	System	05 Sep 2020 19:16:47
	System	05 Sep 2020 19:16:47

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f90db840-cbf4-4566-8312-98be83e51342' User entered 'None (0)'	System	05 Sep 2020 19:16:47
	System	05 Sep 2020 19:16:47

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:39', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f90db840-cbf4-4566-8312-98be83e51342' User entered 'None (0)'	System	05 Sep 2020 19:16:47
	System	05 Sep 2020 19:16:47

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:42', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f90db840-cbf4-4566-8312-98be83e51342' User entered 'No (N)'	System	05 Sep 2020 19:16:47
	System	05 Sep 2020 19:16:47

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-05T13:16:44', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f90db840-cbf4-4566-8312-98be83e51342' User entered '05 Sep 2020 13:16'	System	05 Sep 2020 19:16:47
	System	05 Sep 2020 19:16:47

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 3'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:36', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e9b7a914-48a2-41ea-b76f-f8041808994a'	System	06 Sep 2020 18:13:57
User entered 'No interference with activity (1)'	System	06 Sep 2020 18:13:57

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:45', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e9b7a914-48a2-41ea-b76f-f8041808994a'	System	06 Sep 2020 18:13:57
User entered 'Some interference with activity (2)'	System	06 Sep 2020 18:13:57

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:48', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e9b7a914-48a2-41ea-b76f-f8041808994a' User entered 'None (0)'	System	06 Sep 2020 18:13:57
	System	06 Sep 2020 18:13:57

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:49', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e9b7a914-48a2-41ea-b76f-f8041808994a' User entered 'None (0)'	System	06 Sep 2020 18:13:57
	System	06 Sep 2020 18:13:57

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:50', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e9b7a914-48a2-41ea-b76f-f8041808994a' User entered 'None (0)'	System	06 Sep 2020 18:13:57
	System	06 Sep 2020 18:13:57

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:52', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e9b7a914-48a2-41ea-b76f-f8041808994a' User entered 'None (0)'	System	06 Sep 2020 18:13:57
	System	06 Sep 2020 18:13:57

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:54', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e9b7a914-48a2-41ea-b76f-f8041808994a' User entered 'No (N)'	System	06 Sep 2020 18:13:57
	System	06 Sep 2020 18:13:57

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-06T12:13:56', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'e9b7a914-48a2-41ea-b76f-f8041808994a' User entered '06 Sep 2020 12:13'	System	06 Sep 2020 18:13:57
	System	06 Sep 2020 18:13:57

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 4'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User closed query 'Per DM CLR: Per Diary Dose 2 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 06:04:05
Query 'Per DM CLR: Per Diary Dose 2 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'this severity rating is used if a CM is taken OR to describe the interference with activity. Correct as entered' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:09:53
User opened query 'Per DM CLR: Per Diary Dose 2 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:06:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:49:14', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd1da368-aa99-4b19-b65e-d3f3a76ea344'	System	07 Sep 2020 21:49:31
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Sep 2020 21:49:31

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:49:17', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd1da368-aa99-4b19-b65e-d3f3a76ea344'	System	07 Sep 2020 21:49:31
User entered 'No interference with activity (1)'	System	07 Sep 2020 21:49:31

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:49:19', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd1da368-aa99-4b19-b65e-d3f3a76ea344' User entered 'None (0)'	System	07 Sep 2020 21:49:31
	System	07 Sep 2020 21:49:31

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:49:20', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd1da368-aa99-4b19-b65e-d3f3a76ea344' User entered 'None (0)'	System	07 Sep 2020 21:49:31
	System	07 Sep 2020 21:49:31

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:49:21', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd1da368-aa99-4b19-b65e-d3f3a76ea344' User entered 'None (0)'	System	07 Sep 2020 21:49:31
	System	07 Sep 2020 21:49:31

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:49:25', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd1da368-aa99-4b19-b65e-d3f3a76ea344' User entered 'None (0)'	System	07 Sep 2020 21:49:31
	System	07 Sep 2020 21:49:31

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:49:27', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd1da368-aa99-4b19-b65e-d3f3a76ea344' User entered 'No (N)'	System	07 Sep 2020 21:49:31
	System	07 Sep 2020 21:49:31

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-07T15:49:29', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dd1da368-aa99-4b19-b65e-d3f3a76ea344' User entered '07 Sep 2020 15:49'	System	07 Sep 2020 21:49:31
	System	07 Sep 2020 21:49:31

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 5'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '434c4be7-75d7-4308-8401-fbb4f5c1bf45' User entered 'None (0)'	System	08 Sep 2020 18:05:54
	System	08 Sep 2020 18:05:54

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:44', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '434c4be7-75d7-4308-8401-fbb4f5c1bf45' User entered 'None (0)'	System	08 Sep 2020 18:05:54
	System	08 Sep 2020 18:05:54

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:45', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '434c4be7-75d7-4308-8401-fbb4f5c1bf45' User entered 'None (0)'	System	08 Sep 2020 18:05:54
	System	08 Sep 2020 18:05:54

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:46', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '434c4be7-75d7-4308-8401-fbb4f5c1bf45' User entered 'None (0)'	System	08 Sep 2020 18:05:54
	System	08 Sep 2020 18:05:54

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:47', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '434c4be7-75d7-4308-8401-fbb4f5c1bf45' User entered 'None (0)'	System	08 Sep 2020 18:05:54
	System	08 Sep 2020 18:05:54

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:48', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '434c4be7-75d7-4308-8401-fbb4f5c1bf45' User entered 'None (0)'	System	08 Sep 2020 18:05:54
	System	08 Sep 2020 18:05:54

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:50', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '434c4be7-75d7-4308-8401-fbb4f5c1bf45'	System	08 Sep 2020 18:05:54
User entered 'No (N)'	System	08 Sep 2020 18:05:54

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-08T12:05:52', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '434c4be7-75d7-4308-8401-fbb4f5c1bf45' User entered '08 Sep 2020 12:05'	System	08 Sep 2020 18:05:54
	System	08 Sep 2020 18:05:54

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 6'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:33', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '27720833-d3a2-4c26-b016-57b9dbacb80e' User entered 'None (0)'	System	09 Sep 2020 20:20:59
	System	09 Sep 2020 20:20:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:39', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '27720833-d3a2-4c26-b016-57b9dbacb80e' User entered 'No interference with activity (1)'	System	09 Sep 2020 20:20:59
	System	09 Sep 2020 20:20:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:41', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '27720833-d3a2-4c26-b016-57b9dbacb80e' User entered 'None (0)'	System	09 Sep 2020 20:20:59
	System	09 Sep 2020 20:20:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '27720833-d3a2-4c26-b016-57b9dbacb80e' User entered 'None (0)'	System	09 Sep 2020 20:20:59
	System	09 Sep 2020 20:20:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:49', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '27720833-d3a2-4c26-b016-57b9dbacb80e' User entered 'None (0)'	System	09 Sep 2020 20:20:59
	System	09 Sep 2020 20:20:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:51', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '27720833-d3a2-4c26-b016-57b9dbacb80e' User entered 'None (0)'	System	09 Sep 2020 20:20:59
	System	09 Sep 2020 20:20:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:53', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '27720833-d3a2-4c26-b016-57b9dbacb80e' User entered 'No (N)'	System	09 Sep 2020 20:20:59
	System	09 Sep 2020 20:20:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-09T14:20:55', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '27720833-d3a2-4c26-b016-57b9dbacb80e' User entered '09 Sep 2020 14:20'	System	09 Sep 2020 20:20:59
	System	09 Sep 2020 20:20:59

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
Data entry locked.	System	04 Sep 2020 21:14:04
User entered 'Day 7'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:10', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '635fff3b-b051-43bd-af12-0a7f0070afcd' User entered 'None (0)'	System	10 Sep 2020 19:34:22
	System	10 Sep 2020 19:34:22

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:11', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '635fff3b-b051-43bd-af12-0a7f0070afcd' User entered 'None (0)'	System	10 Sep 2020 19:34:22
	System	10 Sep 2020 19:34:22

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:11', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '635fff3b-b051-43bd-af12-0a7f0070afcd' User entered 'None (0)'	System	10 Sep 2020 19:34:22
	System	10 Sep 2020 19:34:22

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:12', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '635fff3b-b051-43bd-af12-0a7f0070afcd' User entered 'None (0)'	System	10 Sep 2020 19:34:22
	System	10 Sep 2020 19:34:22

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:13', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '635fff3b-b051-43bd-af12-0a7f0070afcd' User entered 'None (0)'	System	10 Sep 2020 19:34:22
	System	10 Sep 2020 19:34:22

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:14', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '635fff3b-b051-43bd-af12-0a7f0070afcd' User entered 'None (0)'	System	10 Sep 2020 19:34:22
	System	10 Sep 2020 19:34:22

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:16', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '635fff3b-b051-43bd-af12-0a7f0070afcd' User entered 'No (N)'	System	10 Sep 2020 19:34:22
	System	10 Sep 2020 19:34:22

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-09-10T13:34:18', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '635fff3b-b051-43bd-af12-0a7f0070afcd' User entered '10 Sep 2020 13:34'	System	10 Sep 2020 19:34:22
	System	10 Sep 2020 19:34:22

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 21:14:04

US3332034

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:46
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 21:14:04

US3332034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 00:39:37

US3332034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 00:39:37

US3332034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 00:39:37

US3332034

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 00:39:37

US3332034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 00:40:37

US3332034

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	12 Sep 2020 00:40:37

US3332034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4) (b) (4)	18 Sep 2020 17:39:51

US3332034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '18 Sep 2020'	Colby Bostock (b) (4)	18 Sep 2020 17:39:51

US3332034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colby Bostock (b) (4) (b) (4)	18 Sep 2020 17:39:51

US3332034

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) Colby Bostock (b) (4) (b) (4)	18 Sep 2020 17:39:51

US3332034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) Colby Bostock (b) (4)	18 Sep 2020 17:39:57

US3332034

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	18 Sep 2020 17:39:57

US3332034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Ty Henry (b) (4)	28 Sep 2020 18:02:58

US3332034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '27 Sep 2020'	Ty Henry (b) (4)	28 Sep 2020 18:02:58

US3332034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Contact Made (CONTACT MADE)'	Ty Henry (b) (4)	28 Sep 2020 18:02:58

US3332034

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	Ty Henry (b) (4)	28 Sep 2020 18:02:58

US3332034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	Ty Henry (b) (4)	28 Sep 2020 18:03:04

US3332034

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	28 Sep 2020 18:03:04

US3332034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:34:19

US3332034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
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). Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 08:03:37
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' answered with '.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:10:15
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:10:11
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). Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:34:33
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 23:34:19

US3332034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[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 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:34:19

US3332034

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'VISIT3'	System	02 Oct 2020 23:34:19

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
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). Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 06:35:45
Query ' Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you' answered with ',' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:21:03
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 21:20:58
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). Thank you' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:03:44
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '16:51'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '02 Oct 2020 16:51'	System	06 Nov 2020 21:20:58
User entered '2 Oct 2020 16:51'	System	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '92'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'bpm'	System	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '12'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'breaths/min'	System	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '98'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '73'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'mmHg'	System	02 Oct 2020 23:35:33

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35

US3332034

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35

US3332034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:42

US3332034

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:35:42

US3332034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:36:36

US3332034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:36:36

US3332034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered '17:10'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:36:36

US3332034

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered '2 Oct 2020 17:10'	System	02 Oct 2020 23:36:36

US3332034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	19 Feb 2021 18:15:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 23:36:41

US3332034

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	02 Oct 2020 23:36:41

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 64'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-10T11:40:45', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'a0432089-f6bd-414d-9ba8-c114c5f50d38'	System	10 Oct 2020 17:40:54
User entered 'No (N)'	System	10 Oct 2020 17:40:54

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-10T11:40:47', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'a0432089-f6bd-414d-9ba8-c114c5f50d38'	System	10 Oct 2020 17:40:54
User entered 'No (N)'	System	10 Oct 2020 17:40:54

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-10T11:40:51', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'a0432089-f6bd-414d-9ba8-c114c5f50d38' User entered '10 Oct 2020 11:40:51'	System	10 Oct 2020 17:40:54
	System	10 Oct 2020 17:40:54

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 71'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-17T14:41:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1333e840-597d-4567-9222-9e8f626c1454'	System	17 Oct 2020 20:41:37
User entered 'No (N)'	System	17 Oct 2020 20:41:37

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-17T14:41:32', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1333e840-597d-4567-9222-9e8f626c1454'	System	17 Oct 2020 20:41:37
User entered 'No (N)'	System	17 Oct 2020 20:41:37

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-17T14:41:34', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1333e840-597d-4567-9222-9e8f626c1454' User entered '17 Oct 2020 14:41:34'	System	17 Oct 2020 20:41:37
	System	17 Oct 2020 20:41:37

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 78'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-24T14:01:53', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '74f3913e-1f3f-4b18-ac9e-c6e9682a83e1' User entered 'No (N)'	System	24 Oct 2020 20:03:41
	System	24 Oct 2020 20:03:41

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-24T14:03:33', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '74f3913e-1f3f-4b18-ac9e-c6e9682a83e1' User entered 'No (N)'	System	24 Oct 2020 20:03:41
	System	24 Oct 2020 20:03:41

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-10-24T14:03:36', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '74f3913e-1f3f-4b18-ac9e-c6e9682a83e1' User entered '24 Oct 2020 14:03:36'	System	24 Oct 2020 20:03:41
	System	24 Oct 2020 20:03:41

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 92'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-11-07T14:00:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1da7bcd-6575-40bb-8bd6-ad26a730972b' User entered 'No (N)'	System	07 Nov 2020 21:00:39
	System	07 Nov 2020 21:00:39

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-11-07T14:00:32', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1da7bcd-6575-40bb-8bd6-ad26a730972b' User entered 'No (N)'	System	07 Nov 2020 21:00:39
	System	07 Nov 2020 21:00:39

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-11-07T14:00:34', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1da7bcd-6575-40bb-8bd6-ad26a730972b' User entered '07 Nov 2020 14:00:34'	System	07 Nov 2020 21:00:39
	System	07 Nov 2020 21:00:39

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered 'Day 99'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-11-14T07:48:25', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c45170db-c383-4324-aa4a-f66f64f79e46'	System	14 Nov 2020 14:48:32
User entered 'No (N)'	System	14 Nov 2020 14:48:32

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-11-14T07:48:27', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c45170db-c383-4324-aa4a-f66f64f79e46'	System	14 Nov 2020 14:48:32
User entered 'No (N)'	System	14 Nov 2020 14:48:32

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (07D96120-DA01-4926-86E1-DB1F32A8FDC6)', Time: '2020-11-14T07:48:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c45170db-c383-4324-aa4a-f66f64f79e46' User entered '14 Nov 2020 07:48:30'	System	14 Nov 2020 14:48:32
	System	14 Nov 2020 14:48:32

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 19:35:19

US3332034

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:46:57
Data entry locked.	System	10 Aug 2020 19:35:19
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 19:35:19

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-11-19T19:04:02', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'da5b479f-a336-41ed-8146-d4e73e39d9ab' User entered 'No (N)'	System	20 Nov 2020 02:04:12
	System	20 Nov 2020 02:04:12

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-11-19T19:04:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'da5b479f-a336-41ed-8146-d4e73e39d9ab'	System	20 Nov 2020 02:04:12
User entered 'No (N)'	System	20 Nov 2020 02:04:12

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-11-19T19:04:06', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'da5b479f-a336-41ed-8146-d4e73e39d9ab' User entered '19 Nov 2020 19:04:06'	System	20 Nov 2020 02:04:12

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-11-27T12:14:14', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1c4739e8-acab-49c7-95fe-f9152d4ef599'	System	27 Nov 2020 19:14:22
User entered 'No (N)'	System	27 Nov 2020 19:14:22

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-11-27T12:14:16', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1c4739e8-acab-49c7-95fe-f9152d4ef599'	System	27 Nov 2020 19:14:22
User entered 'No (N)'	System	27 Nov 2020 19:14:22

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-11-27T12:14:18', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '1c4739e8-acab-49c7-95fe-f9152d4ef599'	System	27 Nov 2020 19:14:22
User entered '27 Nov 2020 12:14:18'	System	27 Nov 2020 19:14:22

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-05T14:04:10', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9e77ba5f-ad7f-4a05-925d-772e780f432c'	System	05 Dec 2020 21:04:17
User entered 'No (N)'	System	05 Dec 2020 21:04:17

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-05T14:04:12', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9e77ba5f-ad7f-4a05-925d-772e780f432c'	System	05 Dec 2020 21:04:17
User entered 'No (N)'	System	05 Dec 2020 21:04:17

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-05T14:04:14', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9e77ba5f-ad7f-4a05-925d-772e780f432c' User entered '05 Dec 2020 14:04:14'	System	05 Dec 2020 21:04:17
	System	05 Dec 2020 21:04:17

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-10T20:17:54', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '92b03a76-5a8a-46bb-8be4-2eb9ee9850ea' User entered 'No (N)'	System	11 Dec 2020 03:18:03
	System	11 Dec 2020 03:18:03

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-10T20:17:56', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '92b03a76-5a8a-46bb-8be4-2eb9ee9850ea' User entered 'No (N)'	System	11 Dec 2020 03:18:03
	System	11 Dec 2020 03:18:03

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-10T20:17:58', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '92b03a76-5a8a-46bb-8be4-2eb9ee9850ea' User entered '10 Dec 2020 20:17:58'	System	11 Dec 2020 03:18:03
	System	11 Dec 2020 03:18:03

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-18T12:00:11', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6bd104a0-988f-46fa-ab57-9dc2f635a7d4'	System	18 Dec 2020 19:00:17
User entered 'No (N)'	System	18 Dec 2020 19:00:17

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-18T12:00:13', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6bd104a0-988f-46fa-ab57-9dc2f635a7d4'	System	18 Dec 2020 19:00:17
User entered 'No (N)'	System	18 Dec 2020 19:00:17

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-18T12:00:15', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6bd104a0-988f-46fa-ab57-9dc2f635a7d4' User entered '18 Dec 2020 12:00:15'	System	18 Dec 2020 19:00:17
	System	18 Dec 2020 19:00:17

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-24T22:59:28', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9fc0b9ac-0eab-4b6c-939e-d31c98e164a9'	System	25 Dec 2020 05:59:35
User entered 'No (N)'	System	25 Dec 2020 05:59:35

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-24T22:59:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9fc0b9ac-0eab-4b6c-939e-d31c98e164a9'	System	25 Dec 2020 05:59:35
User entered 'No (N)'	System	25 Dec 2020 05:59:35

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-24T22:59:32', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9fc0b9ac-0eab-4b6c-939e-d31c98e164a9' User entered '24 Dec 2020 22:59:32'	System	25 Dec 2020 05:59:35
	System	25 Dec 2020 05:59:35

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-31T06:26:19', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6c1535ce-56fe-4357-b1fb-5dc22c6aa596'	System	31 Dec 2020 13:26:29
User entered 'No (N)'	System	31 Dec 2020 13:26:29

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-31T06:26:21', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6c1535ce-56fe-4357-b1fb-5dc22c6aa596'	System	31 Dec 2020 13:26:29
User entered 'No (N)'	System	31 Dec 2020 13:26:29

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2020-12-31T06:26:27', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6c1535ce-56fe-4357-b1fb-5dc22c6aa596' User entered '31 Dec 2020 06:26:27'	System	31 Dec 2020 13:26:29
	System	31 Dec 2020 13:26:29

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-07T21:14:17', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f19ad0a9-1999-4c67-8885-829aa9ab78c8'	System	08 Jan 2021 04:14:24
User entered 'No (N)'	System	08 Jan 2021 04:14:24

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-07T21:14:20', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f19ad0a9-1999-4c67-8885-829aa9ab78c8'	System	08 Jan 2021 04:14:24
User entered 'No (N)'	System	08 Jan 2021 04:14:24

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-07T21:14:22', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f19ad0a9-1999-4c67-8885-829aa9ab78c8' User entered '07 Jan 2021 21:14:22'	System	08 Jan 2021 04:14:24
	System	08 Jan 2021 04:14:24

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-13T07:54:04', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '74f350bf-eff4-4ab8-90d3-825238fa2fc1'	System	13 Jan 2021 14:54:12
User entered 'No (N)'	System	13 Jan 2021 14:54:12

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-13T07:54:06', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '74f350bf-eff4-4ab8-90d3-825238fa2fc1'	System	13 Jan 2021 14:54:12
User entered 'No (N)'	System	13 Jan 2021 14:54:12

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-13T07:54:09', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '74f350bf-eff4-4ab8-90d3-825238fa2fc1' User entered '13 Jan 2021 07:54:09'	System	13 Jan 2021 14:54:12
	System	13 Jan 2021 14:54:12

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-20T21:31:41', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6270a30b-6c9f-436c-9454-49d0c9364c21'	System	21 Jan 2021 04:31:48
User entered 'No (N)'	System	21 Jan 2021 04:31:48

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-20T21:31:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6270a30b-6c9f-436c-9454-49d0c9364c21'	System	21 Jan 2021 04:31:48
User entered 'No (N)'	System	21 Jan 2021 04:31:48

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-20T21:31:46', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '6270a30b-6c9f-436c-9454-49d0c9364c21' User entered '20 Jan 2021 21:31:46'	System	21 Jan 2021 04:31:48
	System	21 Jan 2021 04:31:48

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-28T21:11:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'a9604bbb-d9fb-484e-b72e-83b9712b4211'	System	29 Jan 2021 04:11:49
User entered 'No (N)'	System	29 Jan 2021 04:11:49

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-28T21:11:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'a9604bbb-d9fb-484e-b72e-83b9712b4211'	System	29 Jan 2021 04:11:49
User entered 'No (N)'	System	29 Jan 2021 04:11:49

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-01-28T21:11:45', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'a9604bbb-d9fb-484e-b72e-83b9712b4211'	System	29 Jan 2021 04:11:49
User entered '28 Jan 2021 21:11:45'	System	29 Jan 2021 04:11:49

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-03T21:15:58', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84c78c4c-b783-40f1-8f7b-98d47726651f' User entered 'No (N)'	System	06 Feb 2021 21:00:37
	System	06 Feb 2021 21:00:37

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-03T21:16:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84c78c4c-b783-40f1-8f7b-98d47726651f' User entered 'No (N)'	System	06 Feb 2021 21:00:37
	System	06 Feb 2021 21:00:37

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-03T21:16:03', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '84c78c4c-b783-40f1-8f7b-98d47726651f' User entered '03 Feb 2021 21:16:03'	System	06 Feb 2021 21:00:37
	System	06 Feb 2021 21:00:37

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-11T18:59:30', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c9a0567e-281e-40cb-9439-79b2ba4b7f9b' User entered 'No (N)'	System	12 Feb 2021 01:59:39
	System	12 Feb 2021 01:59:39

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-11T18:59:31', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c9a0567e-281e-40cb-9439-79b2ba4b7f9b' User entered 'No (N)'	System	12 Feb 2021 01:59:39
	System	12 Feb 2021 01:59:39

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-11T18:59:33', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c9a0567e-281e-40cb-9439-79b2ba4b7f9b' User entered '11 Feb 2021 18:59:33'	System	12 Feb 2021 01:59:39
	System	12 Feb 2021 01:59:39

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-17T14:29:16', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9e0bf214-b3f5-411e-b319-3bfe29fa1ad7'	System	17 Feb 2021 21:29:23
User entered 'No (N)'	System	17 Feb 2021 21:29:23

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-17T14:29:18', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9e0bf214-b3f5-411e-b319-3bfe29fa1ad7'	System	17 Feb 2021 21:29:23
User entered 'No (N)'	System	17 Feb 2021 21:29:23

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-17T14:29:20', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9e0bf214-b3f5-411e-b319-3bfe29fa1ad7' User entered '17 Feb 2021 14:29:20'	System	17 Feb 2021 21:29:23
	System	17 Feb 2021 21:29:23

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-24T08:16:36', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'cdb68454-5a56-4726-bdc5-77e48045162d'	System	24 Feb 2021 15:16:45
User entered 'No (N)'	System	24 Feb 2021 15:16:45

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-24T08:16:38', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'cdb68454-5a56-4726-bdc5-77e48045162d' User entered 'No (N)'	System	24 Feb 2021 15:16:45
	System	24 Feb 2021 15:16:45

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-24T08:16:43', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'cdb68454-5a56-4726-bdc5-77e48045162d' User entered '24 Feb 2021 08:16:43'	System	24 Feb 2021 15:16:45
	System	24 Feb 2021 15:16:45

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-05T12:00:18-07:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9fd14e5f-f992-4a3e-9117-d8625d9b685a' User entered 'No (N)'	System	05 Mar 2021 19:00:27
	System	05 Mar 2021 19:00:27

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-05T12:00:19-07:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9fd14e5f-f992-4a3e-9117-d8625d9b685a' User entered 'No (N)'	System	05 Mar 2021 19:00:27
	System	05 Mar 2021 19:00:27

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-05T12:00:24-07:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '9fd14e5f-f992-4a3e-9117-d8625d9b685a' User entered '05 Mar 2021 12:00:24'	System	05 Mar 2021 19:00:27
	System	05 Mar 2021 19:00:27

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-10T08:59:21-07:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'aa19b4c6-bee1-46f9-83f1-da26caa28d92'	System	10 Mar 2021 15:59:27
User entered 'No (N)'	System	10 Mar 2021 15:59:27

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-10T08:59:22-07:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'aa19b4c6-bee1-46f9-83f1-da26caa28d92'	System	10 Mar 2021 15:59:27
User entered 'No (N)'	System	10 Mar 2021 15:59:27

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-10T08:59:24-07:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'aa19b4c6-bee1-46f9-83f1-da26caa28d92'	System	10 Mar 2021 15:59:27
User entered '10 Mar 2021 08:59:24'	System	10 Mar 2021 15:59:27

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-17T04:06:01-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'af966bc2-055b-4311-ba37-d448a8ebc3e8'	System	17 Mar 2021 10:06:09
User entered 'No (N)'	System	17 Mar 2021 10:06:09

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-17T04:06:03-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'af966bc2-055b-4311-ba37-d448a8ebc3e8'	System	17 Mar 2021 10:06:09
User entered 'No (N)'	System	17 Mar 2021 10:06:09

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-17T04:06:06-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'af966bc2-055b-4311-ba37-d448a8ebc3e8' User entered '17 Mar 2021 04:06:06'	System	17 Mar 2021 10:06:09
	System	17 Mar 2021 10:06:09

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-24T21:59:42-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '185b25f4-25ad-4b67-b39a-dbb7d56741fc'	System	25 Mar 2021 03:59:51
User entered 'No (N)'	System	25 Mar 2021 03:59:51

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-24T21:59:44-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '185b25f4-25ad-4b67-b39a-dbb7d56741fc'	System	25 Mar 2021 03:59:51
User entered 'No (N)'	System	25 Mar 2021 03:59:51

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-03-24T21:59:46-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '185b25f4-25ad-4b67-b39a-dbb7d56741fc' User entered '24 Mar 2021 21:59:46'	System	25 Mar 2021 03:59:51
	System	25 Mar 2021 03:59:51

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-01T08:39:45-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dbf52149-6d50-4af5-8c32-830d35da9d44'	System	01 Apr 2021 14:39:52
User entered 'No (N)'	System	01 Apr 2021 14:39:52

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-01T08:39:47-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dbf52149-6d50-4af5-8c32-830d35da9d44'	System	01 Apr 2021 14:39:52
User entered 'No (N)'	System	01 Apr 2021 14:39:52

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-01T08:39:50-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'dbf52149-6d50-4af5-8c32-830d35da9d44'	System	01 Apr 2021 14:39:52
User entered '01 Apr 2021 08:39:50'	System	01 Apr 2021 14:39:52

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-08T22:31:11-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c98ea28b-5b94-4924-a050-7b2567debaea' User entered 'No (N)'	System	09 Apr 2021 04:31:16
	System	09 Apr 2021 04:31:16

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-08T22:31:12-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c98ea28b-5b94-4924-a050-7b2567debaea' User entered 'No (N)'	System	09 Apr 2021 04:31:16
	System	09 Apr 2021 04:31:16

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-08T22:31:14-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'c98ea28b-5b94-4924-a050-7b2567debaea' User entered '08 Apr 2021 22:31:14'	System	09 Apr 2021 04:31:16
	System	09 Apr 2021 04:31:16

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-14T07:58:08-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ace56e04-7b71-4a48-999e-5089c416366a'	System	14 Apr 2021 13:58:19
User entered 'No (N)'	System	14 Apr 2021 13:58:19

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-14T07:58:10-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ace56e04-7b71-4a48-999e-5089c416366a'	System	14 Apr 2021 13:58:19
User entered 'No (N)'	System	14 Apr 2021 13:58:19

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-14T07:58:13-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'ace56e04-7b71-4a48-999e-5089c416366a' User entered '14 Apr 2021 07:58:13'	System	14 Apr 2021 13:58:19
	System	14 Apr 2021 13:58:19

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-21T09:10:12-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f1ec8842-844c-4f02-91ad-7d44a16a88eb' User entered 'No (N)'	System	21 Apr 2021 15:10:20
	System	21 Apr 2021 15:10:20

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-21T09:10:14-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f1ec8842-844c-4f02-91ad-7d44a16a88eb' User entered 'No (N)'	System	21 Apr 2021 15:10:20
	System	21 Apr 2021 15:10:20

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-21T09:10:16-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'f1ec8842-844c-4f02-91ad-7d44a16a88eb' User entered '21 Apr 2021 09:10:16'	System	21 Apr 2021 15:10:20
	System	21 Apr 2021 15:10:20

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-28T07:54:03-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '950bd708-1c3a-4563-8fb8-138e361e7b93'	System	28 Apr 2021 21:04:14
User entered 'No (N)'	System	28 Apr 2021 21:04:14

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

Have you been exposed to someone with 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 (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-28T07:54:05-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '950bd708-1c3a-4563-8fb8-138e361e7b93'	System	28 Apr 2021 21:04:14
User entered 'No (N)'	System	28 Apr 2021 21:04:14

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-04-28T07:54:07-06:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: '950bd708-1c3a-4563-8fb8-138e361e7b93'	System	28 Apr 2021 21:04:14
User entered '28 Apr 2021 07:54:07'	System	28 Apr 2021 21:04:14

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 02:58:28

US3332034

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:58:28
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 02:58:28

US3332034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:10:35

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 06:07:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-27T14:01:48-07:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'fef06599-1a98-42a3-8b27-5feb75d6b690'	System	27 Feb 2021 21:01:53
User entered 'No (N)'	System	27 Feb 2021 21:01:53

US3332034

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:10:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:07:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C0A0DF2-4FFA-41F3-94B8-43ADEAB59A0C)', Time: '2021-02-27T14:01:51-07:00', User OID: 'PatientReportedOutcome (US3332034)', ODM File OID: 'fef06599-1a98-42a3-8b27-5feb75d6b690' User entered '27 Feb 2021 21:01:51'	System	27 Feb 2021 21:01:53
	System	27 Feb 2021 21:01:53

US3332034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Megan Grimmatt (b) (4)	29 Oct 2020 20:16:38

US3332034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '29 Oct 2020'	Megan Grimmatt (b) (4)	29 Oct 2020 20:16:38

US3332034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Megan Grimmatt (b) (4)	29 Oct 2020 20:16:38

US3332034

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	Megan Grimmatt (b) (4)	29 Oct 2020 20:16:38

US3332034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	Megan Grimmatt (b) (4)	29 Oct 2020 20:17:16

US3332034

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 17:56:35
User entered 'I'	System	29 Oct 2020 20:17:16

US3332034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	04 Dec 2020 23:14:11

US3332034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '4 Dec 2020'	Ashley Bragg (b) (4)	04 Dec 2020 23:14:11

US3332034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Contact Made (CONTACT MADE)'	Ashley Bragg (b) (4)	04 Dec 2020 23:14:11

US3332034

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	Ashley Bragg (b) (4)	04 Dec 2020 23:14:11

US3332034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	04 Dec 2020 23:14:17

US3332034

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered 'I'	System	04 Dec 2020 23:14:17

US3332034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:20:48

US3332034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '04 Jan 2021' reason for change: Data Entry Error	(b) (4)	04 Jan 2021 22:21:14
User entered '4 Jan 2021'	(b) (4), (b) (6)	04 Jan 2021 22:20:48

US3332034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:20:48

US3332034

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:20:48

US3332034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:21:06

US3332034

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered 'I'	System	04 Jan 2021 22:21:06

US3332034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 23:21:16

US3332034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 23:21:16

US3332034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 23:21:16

US3332034

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 23:21:16

US3332034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 23:21:21

US3332034

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered 'I'	System	29 Jan 2021 23:21:21

US3332034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:51:24

US3332034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User closed query 'Per GCL Lab Recon: Immuno: Sample dated 19 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 17:11:03
Query 'Per GCL Lab Recon: Immuno: Sample dated 19 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' answered with 'correction sent to lab' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:08:51
User opened query 'Per GCL Lab Recon: Immuno: Sample dated 19 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 14:43:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4), (b) (6)	20 Feb 2021 00:51:24

US3332034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[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 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:51:24

US3332034

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered 'VISIT4'	System	20 Feb 2021 00:51:24

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'No (N)'	Ashley Bragg (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered empty.	System	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered empty.	System	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered empty.	System	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered empty.	System	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	Ashley Bragg (b) (4)	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered empty.	System	30 Mar 2021 22:56:30

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06

US3332034

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06

US3332034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:51:35

US3332034

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:51:35

US3332034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	Kenadie Hamblin (b) (4)	18 Mar 2021 19:01:55

US3332034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '19 Feb 2021'	Kenadie Hamblin (b) (4)	18 Mar 2021 19:01:55

US3332034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '16:30'	Kenadie Hamblin (b) (4)	18 Mar 2021 19:01:55

US3332034

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered '19 Feb 2021 16:30'	System	18 Mar 2021 19:01:55

US3332034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:51:42

US3332034

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:14:06
User entered 'I'	System	20 Feb 2021 00:51:42

US3332034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:53
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	31 Mar 2021 17:29:39

US3332034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:53
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '31 Mar 2021'	Ashley Bragg (b) (4)	31 Mar 2021 17:29:39

US3332034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:53
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	31 Mar 2021 17:29:39

US3332034

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:53
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	31 Mar 2021 17:29:39

US3332034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:53
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	31 Mar 2021 17:29:48

US3332034

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:24:53
User entered 'I'	System	31 Mar 2021 17:29:48

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:10:35

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:15:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:08:17
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated "30NOV2020 and 02DEC2020" are reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 04:49:20
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated "30NOV2020 and 02DEC2020" are reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 22:55:48
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated "30NOV2020 and 02DEC2020" are reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 08:49:03
User entered '25 Nov 2020'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:33:08

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:10:35

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:15:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:08:17
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '12:30'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:33:08

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:10:35

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:15:55
User entered '25 Nov 2020 12:30'	System	25 Nov 2020 22:33:08

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:10:35

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:15:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:08:17
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:33:08

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:10:35

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:15:55
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:08:17
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:33:08

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 1 (Day 1)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '18 Nov 2020'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:30:41
User entered empty.	System	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:23

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 2 (Day 2)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Nov 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:30:41
User entered empty.	System	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:39:27

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 3 (Day 3)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '20 Nov 2020'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:41:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:30:41
User entered empty.	System	25 Nov 2020 22:41:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:41:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:41:11

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 4 (Day 4)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '21 Nov 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:42:50

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:30:41
User entered empty.	System	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:42:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 5 (Day 5)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '22 Nov 2020'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:44:19

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:30:41
User entered empty.	System	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:44:19

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 6 (Day 6)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '23 Nov 2020'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:47:52

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:30:41
User entered empty.	System	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:47:52

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 7 (Day 7)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '24 Nov 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:30:41
User entered empty.	System	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:30:41
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:49:26

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 8 (Day 8)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '25 Nov 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '96'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '98.4' F	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	Ashley Bragg (b) (4)	25 Nov 2020 22:51:02

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:42:16

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Nov 2020 15:43:10

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '95'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	28 Dec 2020 22:51:50

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:51:50

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '29 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '96'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:53:15

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '95'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User entered '%'	System	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:10:35

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:54:44

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 07:29:34
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' answered with 'ADDED' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 22:55:31
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 25 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:00:34
User entered '25 Nov 2020'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:35:53

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

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 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:53

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

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 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 22:36:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 22:36:03
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bragg (b) (4)	25 Nov 2020 22:36:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 22:35:53
User entered empty.	System	25 Nov 2020 22:35:53
	Ashley Bragg (b) (4)	25 Nov 2020 22:35:53
	(b) (4)	

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '25 Nov 2020'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:53

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:53

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	Ashley Bragg (b) (4)	25 Nov 2020 22:35:53

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

[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 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	Ashley Bragg (b) (4)	25 Nov 2020 22:35:53

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	Ashley Bragg (b) (4)	25 Nov 2020 22:35:53

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:06
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	Ashley Bragg (b) (4)	25 Nov 2020 22:35:53

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:10:35

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:06
User entered '0'	System	25 Nov 2020 22:36:03

US3332034

Folder: Covid-19 Assessment 25 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:10:35

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	25 Nov 2020 22:33:12

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:10:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:10:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this "DAY 3 SALIVA" sample is recorded as collected on "30NOV 2020", however in EDC, it is recorded as collected on "27 NOV 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in Preclarus PPD portal as necessary. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 12:37:14
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this "DAY 3 SALIVA" sample is recorded as collected on "30NOV 2020", however in EDC, it is recorded as collected on "27 NOV 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in Preclarus PPD portal as necessary. Thank you. ' answered with 'sent DCF to preclarus- correct date is 11.27.20' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:28:06
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this "DAY 3 SALIVA" sample is recorded as collected on "30NOV 2020", however in EDC, it is recorded as collected on "27 NOV 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in Preclarus PPD portal as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:08:38
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this "DAY 3 SALIVA" sample is recorded as collected on "230NOV 2020", however in EDC, it is recorded as collected on "27 NOV 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in Preclarus PPD portal as necessary. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:08:25

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:10:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this "DAY 3 SALIVA" sample is recorded as collected on "230NOV 2020", however in EDC, it is recorded as collected on "27 NOV 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in Preclarus PPD portal as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:08:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User closed query 'Per GCL Lab Reconciliation Requrey: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 13:05:11
Query 'Per GCL Lab Reconciliation Requrey: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'information unavailable ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 00:32:41
User opened query 'Per GCL Lab Reconciliation Requrey: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:49:51
User closed query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 27NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:49:51
Query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 27NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'accession # 1f600358952. ' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:34:24
User opened query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 27NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 10:44:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

2017 of 2790

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:10:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:10:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:10:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:10:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '02 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:10:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:10:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this "DAY 9 SALIVA" sample is recorded as collected on "02 DEC 2020", however in EDC, it is recorded as collected on "04 DEC 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in Preclarus PPD portal as necessary. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 12:37:28
Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this "DAY 9 SALIVA" sample is recorded as collected on "02 DEC 2020", however in EDC, it is recorded as collected on "04 DEC 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in Preclarus PPD portal as necessary. Thank you. ' answered with 'dcf submitted to precalrus correct date is 12.4.20' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:28:57
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, this "DAY 9 SALIVA" sample is recorded as collected on "02 DEC 2020", however in EDC, it is recorded as collected on "04 DEC 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in Preclarus PPD portal as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:07:12
User closed query 'Per GCL Lab Reconciliation Requrey: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 13:05:23
Query 'Per GCL Lab Reconciliation Requrey: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'information unavailable ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 00:32:56

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the Accession number. Please provide the tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:50:03
User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 04DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:50:03
Query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 04DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'accession # 1f600358952' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 23:35:00
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 04DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 10:45:06
User entered '04 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:10:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:10:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:10:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:10:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:10:35

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:10:35

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:39
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:48:23

US3332034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:44:16

US3332034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:44:16

US3332034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[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 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:44:16

US3332034

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
User entered 'SICKD1'	System	28 Dec 2020 22:44:16

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '12:45'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
User entered '25 Nov 2020 12:45'	System	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '67.0' in	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56
DataPoint set to visible.	System	28 Dec 2020 22:44:16

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '140.0' kg	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56
DataPoint set to visible.	System	28 Dec 2020 22:44:16

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '85'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
User entered 'bpm'	System	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '20'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
User entered 'breaths/min'	System	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '98'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
User entered 'mmHg'	System	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
User signature succeeded.	James Peterson (b) (4)	28 Apr 2021 08:50:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:55:35
User closed query 'Per source, it is 59, please verify.' (Site from CRA).		26 Apr 2021 15:55:07
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		26 Apr 2021 08:01:06
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per Investigator. ' (Site from System).	Kenadie Hamblin (b) (4) (b) (4)	23 Apr 2021 19:55:32
Query 'Per source, it is 59, please verify.' answered with 'Data entered is correct. ' (Site from CRA).	Kenadie Hamblin (b) (4) (b) (4)	23 Apr 2021 19:55:02
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Apr 2021 22:02:23
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 22:02:23
User entered '59' reason for change: Data Entry Error		22 Apr 2021 22:02:23
User opened query 'Per source, it is 59, please verify.' (Site from CRA).		22 Apr 2021 17:05:33
DataPoint Un-verified.		22 Apr 2021 17:04:53
DataPoint Verified.		22 Apr 2021 17:04:50
User signature succeeded.	James Peterson (b) (4) (b) (4)	23 Feb 2021 13:31:25
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 05:41:38

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 22:46:26
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		28 Dec 2020 22:45:56
User entered '58'	(b) (4), (b) (6)	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
User entered 'mmHg'	System	28 Dec 2020 22:45:56

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02

US3332034

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02

US3332034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:05:54
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:46:47

US3332034

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:05:54
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:46:47

US3332034

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:10:35

[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 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:47:04

US3332034

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:10:35

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:56:02
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:06:01
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:47:04

US3332034

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		13 Jan 2021 19:04:33
User entered 'Yes (Y)'	Bradley Young (b) (4)	11 Jan 2021 21:27:46

US3332034

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:04:33
User entered '11 Jan 2021'	Bradley Young (b) (4)	11 Jan 2021 21:27:46

US3332034

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[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 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 19:04:33
User entered 'Clinic (Clinic)'	Bradley Young (b) (4)	11 Jan 2021 21:27:46

US3332034

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 21:27:46

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:28:05

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[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 23:44:44
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:07
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 22:18:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:37:52

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:28:05

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:07
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 10:47:27
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 22:19:04
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 22:18:39
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 12:37:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:37:52

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:28:05

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Placebo (Placebo)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:28:05

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:51:56
User entered 'Placebo (Placebo)'	Bradley Young (b) (4)	11 Jan 2021 21:28:05

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 06:51:56
User entered 'Placebo (Placebo)'	Bradley Young (b) (4)	11 Jan 2021 21:28:05

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:28:05

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '1'	System	11 Jan 2021 21:28:05

US3332034

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'I'	System	11 Jan 2021 21:28:05

US3332034

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4)	11 Jan 2021 21:29:45
	Bradley Young (b) (4)	

US3332034

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4)	11 Jan 2021 21:29:45
	Bradley Young (b) (4)	

US3332034

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered empty.	System	11 Jan 2021 21:29:45
DataPoint set to visible.	System	11 Jan 2021 21:28:05

US3332034

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4)	11 Jan 2021 21:29:45
	Bradley Young (b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4)	11 Jan 2021 21:29:45
	Bradley Young (b) (4)	

US3332034

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered empty.	System	11 Jan 2021 21:29:45
DataPoint set to visible.	System	11 Jan 2021 21:28:05

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User accepted default value 'Pre-Dose (PREDOSE)'	Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '12:01'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '11 Jan 2021 12:01'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '99.2' F	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (Oral)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '95'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'bpm'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '16'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'breaths/min'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '116'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '76'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4)	11 Jan 2021 21:29:45
	Bradley Young (b) (4)	

US3332034

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered empty.	System	11 Jan 2021 21:29:45
DataPoint set to visible.	System	11 Jan 2021 21:28:05

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User accepted default value 'Post-Dose (POSTDOSE)'	Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '12:59'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '11 Jan 2021 12:59'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '98.5' F	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (Oral)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4)	11 Jan 2021 21:29:45
	Bradley Young (b) (4)	

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '95'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'bpm'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '14'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'breaths/min'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '108'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '74'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:45

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	11 Jan 2021 21:29:45

US3332034

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:53

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:29:53

US3332034

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:30:35

US3332034

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:30:35

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Urine (URINE)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:30:35

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Negative (NEGATIVE)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:30:35

US3332034

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:30:35

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:30:35

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:30:35

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered empty.	System	11 Jan 2021 21:30:35

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:07

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:07

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

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 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:07

US3332034

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mRNA-1273'	System	11 Jan 2021 21:31:07
DataPoint set to visible.	System	11 Jan 2021 21:28:05

US3332034

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:07

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '12:25'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:07

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '11 Jan 2021 12:25'	System	11 Jan 2021 21:31:07

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:59:03
User entered 'Right Arm (RIGHT ARM)'	Bradley Young (b) (4)	11 Jan 2021 21:31:07

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'ONCE'	System	11 Jan 2021 21:31:07

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

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 21:31:07

US3332034

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:38

US3332034

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:38

US3332034

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11:23'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:38

US3332034

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '11 Jan 2021 11:23'	System	11 Jan 2021 21:31:38

US3332034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:51

US3332034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11 Jan 2021'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:51

US3332034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '11:16'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:51

US3332034

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:35

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '11 Jan 2021 11:16'	System	11 Jan 2021 21:31:51

US3332034

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

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Bradley Young (b) (4)	11 Jan 2021 21:31:56

US3332034

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

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'I'	System	11 Jan 2021 21:31:56

US3332034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:43

US3332034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:43

US3332034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:43

US3332034

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:43

US3332034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 21:33:48

US3332034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'I'	System	18 Jan 2021 21:33:48

US3332034

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '1'	System	18 Jan 2021 21:33:48
DataPoint set to visible.	System	18 Jan 2021 21:33:48

US3332034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:52:00

US3332034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:52:00

US3332034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[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 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:52:00

US3332034

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'OLD29'	System	20 Feb 2021 00:52:00

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '15:58'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '19 Feb 2021 15:58'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '100'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'bpm'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'breaths/min'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '90'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 08:45:54
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per Investigator' (Site from System).	(b) (4), (b) (6)	20 Feb 2021 00:54:58
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		20 Feb 2021 00:53:49
User entered '55'	(b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '17:18'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '19 Feb 2021 17:18'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '94'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'bpm'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '12'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'breaths/min'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '107'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '77'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	20 Feb 2021 00:53:49

US3332034

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:55:10

US3332034

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:55:10

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:48

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:48

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:48

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:48

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User closed query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:29:16
Query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you!' ' answered with 'REMOVED' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:38:15
User opened query 'Per CDM: "Was FSH sample collected?" is answered as NO, however date and time are collected. If date and time belongs to FSH then please consider changing answer from No to Yes. If date and time belongs to Pregnancy test, then please remove date and time. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:15:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:48

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:37:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:37:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:48

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:37:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:37:42
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '16:20'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:57:48

US3332034

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered empty.	System	19 Mar 2021 14:37:42
User entered '19 Feb 2021 16:20'	System	20 Feb 2021 00:57:48

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

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 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mRNA-1273'	System	20 Feb 2021 00:58:13
DataPoint set to visible.	System	18 Jan 2021 21:33:48

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '16:47'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '19 Feb 2021 16:47'	System	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4)	20 Feb 2021 00:59:03
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	20 Feb 2021 00:59:03
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	20 Feb 2021 00:58:13
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'ONCE'	System	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'INTRAMUSCULAR'	System	20 Feb 2021 00:58:13

US3332034

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:59:20

US3332034

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'I'	System	20 Feb 2021 00:59:20

US3332034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:41:54

US3332034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:41:54

US3332034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:41:54

US3332034

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:41:54

US3332034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 21:42:02

US3332034

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'I'	System	26 Feb 2021 21:42:02

US3332034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:39:56

US3332034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:39:56

US3332034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[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 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:39:56

US3332034

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'OLD57'	System	24 Mar 2021 22:39:56

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '15:47'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '24 Mar 2021 15:47'	System	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '108'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'bpm'	System	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'breaths/min'	System	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '100'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '67'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered 'mmHg'	System	24 Mar 2021 22:40:45

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44

US3332034

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:35

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44

US3332034

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:55

US3332034

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:40:55

US3332034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:41:14

US3332034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:41:14

US3332034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '15:40'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 22:41:14

US3332034

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:35

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:44:44
User entered '24 Mar 2021 15:40'	System	24 Mar 2021 22:41:14

US3332034

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:10:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:26
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	25 Nov 2020 22:52:56

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Conjunctivitis, LLT: Conjunctivitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Nov 2020 00:02:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Nov 2020 00:02:05
Data point term sent to Coder	System	25 Nov 2020 22:54:32
User entered 'R eye conjunctivitis'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '21 Nov 2020'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User entered empty.	System	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '22 Nov 2020'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User entered empty.	System	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Nov 2020 19:51:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Nov 2020 19:51:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Nov 2020 19:51:42
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 22:54:11
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'None (NONE)'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per DM LR RequeryAs per response,subject did not use medication confirmed per source,howeverconmed #6 is still recorded on conmed page.Kindly consider to verify if data recorded on comed page #6 should be removed else please clarify and update data appropriately. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 05:27:42
Query 'Per DM LR RequeryAs per response,subject did not use medication confirmed per source,howeverconmed #6 is still recorded on conmed page.Kindly consider to verify if data recorded on comed page #6 should be removed else please clarify and update data appropriately. ' answered with 'removed, subject did not take. thanks.' (Site from DM).	Ashley Bragg (b) (4) (b) (4)	18 Jan 2021 17:15:10
User opened query 'Per DM LR RequeryAs per response,subject did not use medication confirmed per source,howeverconmed #6 is still recorded on conmed page.Kindly consider to verify if data recorded on comed page #6 should be removed else please clarify and update data appropriately. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 08:13:16
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 08:13:16
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'subject did not use medication confirmed per source' (Site from DM).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 16:28:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM). User entered 'I'	(b) (4), (b) (6) (b) (4) Ashley Bragg (b) (4) (b) (4)	11 Jan 2021 02:48:31 25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

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 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	Ashley Bragg (b) (4) (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	Ashley Bragg (b) (4)	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User entered '0'	System	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22
User entered 'I'	System	25 Nov 2020 22:54:11

US3332034

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:27:22

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Jan 2021 16:17:13
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:28
User entered	System	05 Jan 2021 20:50:43
'USA-US202-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	05 Jan 2021 20:50:43

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Gallbladder disorders NEC, PT: Biliary dyskinesia, LLT: Biliary dyskinesia - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 19:59:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 19:59:30
	(b) (4)	
Data point term sent to Coder	System	04 Jan 2021 19:43:04
User entered 'BILIARY DYSKINESIA'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '01 Nov 2020'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '31 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error		04 Jan 2021 20:12:49
User entered 'Grade 3/Severe (Grade 3/Severe)'		04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'PV Query: As there were no reported complications and the subject was not hospitalized overnight, please consider updating seriousness criteria to medically important event. Or please provide the disability/incapacity.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:16:31
Query 'PV Query: As there were no reported complications and the subject was not hospitalized overnight, please consider updating seriousness criteria to medically important event. Or please provide the disability/incapacity.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	30 Jan 2021 00:40:04
DataPoint Un-verified.	(b) (4), (b) (6)	30 Jan 2021 00:39:12
User entered '0' reason for change: Data Entry Error		30 Jan 2021 00:39:12
User opened query 'PV Query: As there were no reported complications and the subject was not hospitalized overnight, please consider updating seriousness criteria to medically important event. Or please provide the disability/incapacity.' (Site from Safety).		21 Jan 2021 14:55:16
DataPoint Verified.		14 Jan 2021 17:40:32
User entered '1'		04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Un-verified.	(b) (4)	30 Jan 2021 00:39:12
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Jan 2021 00:39:12
DataPoint Verified.		14 Jan 2021 17:40:32
User entered '0'		04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:07
Signature has been broken.	(b) (4)	
	Kenadie Hamblin (b) (4)	07 Apr 2021 15:01:42
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Kenadie Hamblin (b) (4)	07 Apr 2021 15:01:42
	(b) (4)	
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:55:31
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 00:38:55
DataPoint Un-verified.	(b) (4), (b) (6)	30 Jan 2021 00:37:09
User entered '0' reason for change: Data Entry Error		30 Jan 2021 00:37:09
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		26 Jan 2021 05:44:38
DataPoint Verified.		14 Jan 2021 17:40:32
User entered '1'		04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

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 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:32:01
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'There is no record of the subject being tested for covid-19.' (Site from Safety).	Sean Hansen (b) (4) (b) (4)	08 Feb 2021 20:30:09
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:09:10
User closed query 'PV Query: As there were no reported complications and the subject was not hospitalized overnight, please consider updating seriousness criteria to medically important event.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 16:17:27
User closed query 'PV Query: Please provide the test which indicated the subject had biliary dyskinesia. Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Jan 2021 16:17:24
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
Query 'PV Query: Please provide the test which indicated the subject had biliary dyskinesia. Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated narrative ' (Site from Safety).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 16:31:59
Query 'PV Query: As there were no reported complications and the subject was not hospitalized overnight, please consider updating seriousness criteria to medically important event.' answered with 'per pi' (Site from Safety).	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 16:31:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTS ABDOMINAL PAIN STARTING APPROXIMATELY 11.1.20. PAIN WORSENER TO THE POINT WHERE AN ER VISIT WAS ATTENDED 12/15/20 AND TESTING INDICATED BILIARY DYSKINESIA. SURGICAL INTERVENTION WAS SUGGESTED AND THE SUBJECT SCHEDULED THE PROCEDURE. SUBJECT WAS DISCHARGED FROM THE ER THE SAME DAY. SUBJECT RETURNED TO HOSPITAL 12/31/20 FOR OUTPATIENT LAPAROSCOPIC CHOLECYSTECTOMY AND WAS SENT HOME LATER THAT DAY. NO COMPLICATIONS. /**per query, the laparoscopic cholecystectomy was used to diagnose the postoperative term biliary dyskinesia' reason for change: Data Entry Error	Colby Bostock (b) (4) (b) (4)	14 Jan 2021 16:31:40
User opened query 'PV Query: As there were no reported complications and the subject was not hospitalized overnight, please consider updating seriousness criteria to medically important event.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:55:30
User opened query 'PV Query: Please provide the test which indicated the subject had biliary dyskinesia. Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:55:01
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Jan 2021 20:12:49
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Jan 2021 20:12:49
User entered 'Subject reports abdominal pain starting approximately 11.1.20. Pain worsened to the point where an ER visit was attended 12/15/20 and testing indicated biliary dyskinesia. Surgical intervention was suggested and the subject scheduled the procedure. Subject was discharged from the ER the same day. Subject returned to hospital 12/31/20 for outpatient laparoscopic cholecystectomy and was sent home later that day. No complications.' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 20:12:49

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Jan 2021 19:42:38
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 19:42:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 19:42:38

US3332034

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 19:42:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 20:17:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 20:17:41
	(b) (4)	
Data point term sent to Coder	System	04 Jan 2021 20:16:20
User entered 'GASTRO ESOPHAGEAL REFLUX DISEASE'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '01 Oct 2020'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

US3332034

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'MED ADDED ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 04:57:29
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 00:51:41
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 05:45:06
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

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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 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:15:53

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 20:15:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 20:15:53

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Hepatic and biliary neoplasms benign, HLT: Hepatobiliary neoplasms benign, PT: Haemangioma of liver, LLT: Hemangioma of liver - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 20:55:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Jan 2021 20:55:31
	(b) (4)	
Data point term sent to Coder	System	04 Jan 2021 20:54:53
User entered 'LIVER HEMANGIOMA'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '15 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05
	(b) (4), (b) (6)	

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 23:33:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 23:33:40
DataPoint Un-verified.	Colby Bostock (b) (4)	14 Jan 2021 23:33:40
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Colby Bostock (b) (4)	14 Jan 2021 23:33:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 20:54:05
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 23:33:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 23:33:40
DataPoint Un-verified.	Colby Bostock (b) (4)	14 Jan 2021 23:33:40
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Colby Bostock (b) (4)	14 Jan 2021 23:33:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 20:54:05
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 23:33:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Jan 2021 23:33:40
DataPoint Un-verified.	Colby Bostock (b) (4)	14 Jan 2021 23:33:40
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Colby Bostock (b) (4)	14 Jan 2021 23:33:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 20:54:05
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered '0'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

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 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	14 Jan 2021 17:40:32
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:54:05
	(b) (4), (b) (6)	

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Jan 2021 20:54:05

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if the subject was diagnosed with COVID-19. If no, please update the actual diagnosis or add the individual symptoms as separate entries. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:07:16
Query 'Per MM, please confirm if the subject was diagnosed with COVID-19. If no, please update the actual diagnosis or add the individual symptoms as separate entries. ' answered with 'see page 47 of guidelines- entered per guidelines correct as entered ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:01:12
User opened query 'Per MM, please confirm if the subject was diagnosed with COVID-19. If no, please update the actual diagnosis or add the individual symptoms as separate entries. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:27:19
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 22:59:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 22:59:41
Data point term sent to Coder	System	09 Mar 2021 22:59:05
User entered 'COVID-LIKE ILLNESS'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'Yes (Y)'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '18 Nov 2020'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 22:58:48

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '11 Dec 2020'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 22:58:48

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'No (N)'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:58:48

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered 'I'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered '0'	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:58:48

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Mar 2021 17:27:52
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	09 Mar 2021 22:58:48
	(b) (4)	

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 22:58:48

US3332034

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 22:58:48

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Apr 2021 08:42:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 08:42:02
Data point term sent to Coder	(b) (4)	20 Apr 2021 21:31:20
User entered 'TRANSIENT TACHYCARDIA'	System	20 Apr 2021 21:31:05
	(b) (4), (b) (6)	

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

Death

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	03 May 2021 14:45:39
User closed query 'Per MM: Please review and confirm the relationship to IP and update, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 04:47:23
Query 'Per MM: Please review and confirm the relationship to IP and update, as appropriate.' answered with 'Data entry error corrected' (Site from DM).	Ashley Bragg (b) (4) (b) (4)	28 Apr 2021 16:27:00
Signature has been broken.	Ashley Bragg (b) (4) (b) (4)	28 Apr 2021 16:26:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	28 Apr 2021 16:26:15
User opened query 'Per MM: Please review and confirm the relationship to IP and update, as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 21:09:48
User signature succeeded.	James Peterson (b) (4) (b) (4)	23 Apr 2021 22:29:17
User entered 'Related (RELATED)'	(b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

None

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Apr 2021 22:29:17
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 21:31:05

US3332034

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 21:31:05

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:10:35

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Aug 2020 17:51:29

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 18:04:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:04:18
Data point term sent to Coder	System	17 Aug 2020 18:03:21
User entered 'Celexa'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:02:48

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Anxiety'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '20'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'mg (mg)'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'once daily (QD)'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
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) (4), (b) (6)	19 Aug 2020 09:53:52
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 'Entered per eCRF guidelines' (Site from System).	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:10:02
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	17 Aug 2020 18:02:48
User entered 'un UNK 2016'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:02:48

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	17 Aug 2020 18:02:48
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 18:02:48

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 18:02:48

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 18:02:48

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 18:06:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:06:23
Data point term sent to Coder	System	17 Aug 2020 18:05:28
User entered 'Trazadone'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:05:02

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Insomnia'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '50'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'mg (mg)'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'as needed (PRN)'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
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) (4), (b) (6)	19 Aug 2020 09:54:04
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 'Entered per eCRF guidelines' (Site from System).	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:10:14
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	17 Aug 2020 18:05:02
User entered 'un Apr 2020'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:05:02

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	17 Aug 2020 18:05:02
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 18:05:02

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 18:05:02

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 18:05:02

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 18:07:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 18:07:09
Data point term sent to Coder	System	17 Aug 2020 18:06:31
User entered 'Aspirin'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:06:21

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:21:45
Query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' answered with 'Entered as no due to medication not being prophylactic in anticipation of injection symptoms.' (Site from DM).	Ty Henry (b) (4) (b) (4)	11 Sep 2020 19:33:14
User opened query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 11:03:07
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:06:21

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Cardiac Prophylaxis'	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '81'	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'mg (mg)'	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'once daily (QD)'	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Oral (ORAL)'	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
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) (4), (b) (6)	19 Aug 2020 09:54:16
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 'Entered per eCRF guidelines' (Site from System).	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:09:40
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	17 Aug 2020 18:06:21
User entered 'un UNK 2010'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:06:21

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '0'	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Yes (Y)'	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'No (N)'	Ty Henry (b) (4)	17 Aug 2020 18:06:21
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 18:06:21

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 18:06:21

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 18:06:21

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 00:16:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	11 Nov 2020 00:16:41
Data point term sent to Coder	System	11 Nov 2020 00:15:40
Coding entries removed.	(b) (4), (b) (6)	11 Nov 2020 00:15:29
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Aug 2020 18:10:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	17 Aug 2020 18:10:23
Data point term sent to Coder	System	17 Aug 2020 18:09:35
User entered 'Mirena'	Ty Henry (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:15:29
User entered 'No (N)'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'PREGNANCY PROPHYLAXIS' reason for change: New Information	(b) (4) (b) (4), (b) (6)	11 Nov 2020 00:15:29
User entered 'Contraception'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '20' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 18:09:08
User entered '200' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:08:26
User entered '20' reason for change: Data Entry Error		29 Oct 2020 22:38:27
User entered '1'	Ty Henry (b) (4)	17 Aug 2020 18:08:54
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 18:08:26
User entered 'Other (OTHER)'	(b) (4), (b) (6)	
	Ty Henry (b) (4)	17 Aug 2020 18:08:54
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per CDM: "If Dose unit is Other, specify" is recorded as 'MCG', however, dose unit 'MCG' is provided in the ecrf dropdown. Please consider selecting "ug" from dropdown instead of selecting other and entering mcg. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 07:56:07
Query 'Per CDM: "If Dose unit is Other, specify" is recorded as 'MCG', however, dose unit 'MCG' is provided in the ecrf dropdown. Please consider selecting "ug" from dropdown instead of selecting other and entering mcg. Thank you!' answered with ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:09:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:08:26
User opened query 'Per CDM: "If Dose unit is Other, specify" is recorded as 'MCG', however, dose unit 'MCG' is provided in the ecrf dropdown. Please consider selecting "ug" from dropdown instead of selecting other and entering mcg. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:34:29
User entered 'MCG' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 22:38:27
User entered 'Device'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per DM CLR: Frequency=Once, however, the medication is still ongoing. Please review if Once every 5 years is the more appropriate way to record this.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 05:52:29
' (Site from DM).		
Query 'Per DM CLR: Frequency=Once, however, the medication is still ongoing. Please review if Once every 5 years is the more appropriate way to record this.	(b) (4), (b) (6)	29 Oct 2020 22:38:33
' answered with 'UPDATED' (Site from DM).		
User entered 'once daily (QD)' reason for change:	(b) (4), (b) (6)	29 Oct 2020 22:38:27
Data Entry Error		
User opened query 'Per DM CLR: Frequency=Once, however, the medication is still ongoing. Please review if Once every 5 years is the more appropriate way to record this.	(b) (4), (b) (6)	13 Oct 2020 06:31:18
' (Site from DM).		
User entered 'once (ONCE)'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Other (OTHER)'	Ty Henry (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Intrauterine'	Ty Henry (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
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) (4), (b) (6)	19 Aug 2020 09:54:24
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 'Entered per eCRF guidelines' (Site from System).	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:09:21
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	17 Aug 2020 18:08:54
User entered 'un Nov 2015'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ty Henry (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)' reason for change: New Information	(b) (4) Bradley Young (b) (4)	27 Jan 2021 15:56:11
User entered 'Yes (Y)'	Ty Henry (b) (4) (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '9 Nov 2020' reason for change: New Information	(b) (4) Bradley Young (b) (4)	27 Jan 2021 15:56:11
User entered empty.	Ty Henry (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	Ty Henry (b) (4)	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User entered '1'	System	29 Oct 2020 22:38:27
User entered empty.	System	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User entered '1'	System	29 Oct 2020 22:38:27
User entered empty.	System	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:51
User entered '804 (804)'	System	29 Oct 2020 22:38:27
User entered empty.	System	17 Aug 2020 18:08:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
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)	04 Dec 2020 23:24:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 23:24:17
Data point term sent to Coder	System	04 Dec 2020 23:23:15
User entered 'Influenza vaccine'	Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Influenza prophylaxis'	Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0.5'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'mL (mL)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'once (ONCE)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '12 Oct 2020'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '12 Oct 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User entered empty.	System	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User entered empty.	System	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:19
User entered empty.	System	04 Dec 2020 23:22:30

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 22:52:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 22:52:44
Data point term sent to Coder	System	09 Mar 2021 22:52:01
Coding entries removed.	Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:51:58
User signature succeeded.	James Peterson (b) (4) (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 00:57:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 00:57:27
Data point term sent to Coder	System	30 Jan 2021 00:56:26
Coding entries removed.	(b) (4), (b) (6)	30 Jan 2021 00:56:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 23:27:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 23:27:01
Data point term sent to Coder	System	04 Dec 2020 23:26:17
User entered 'Tylenol'	Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User closed query 'Per DM CLR-RQ: Response noted. However, please note that there is no AE entered for SORE THROAT AND FEVER. Please review and add a medical condition and all applicable details to the AE eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 05:44:43
Query 'Per DM CLR-RQ: Response noted. However, please note that there is no AE entered for SORE THROAT AND FEVER. Please review and add a medical condition and all applicable details to the AE eCRF as appropriate. Otherwise, clarify.' answered with 'AE ADDED FOR COVID-LIKE ILLNESS' (Site from DM).	Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:52:13
Signature has been broken.	Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:51:58
User entered 'COVID-LIKE ILLNESS' reason for change: Data Entry Error	Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:51:58
User opened query 'Per DM CLR-RQ: Response noted. However, please note that there is no AE entered for SORE THROAT AND FEVER. Please review and add a medical condition and all applicable details to the AE eCRF as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 03:26:22
User signature succeeded.	James Peterson (b) (4) (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per DM CLR: Please note that there are no AEs that match this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:13:26
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:11:17

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'see sx log taken for sore throat EVENT NAME UPDATED ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 00:56:47
Query 'Per DM CLR: Please note that there are no AEs that match this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'see sx log taken for sore throat EVENT NAME UPDATED ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 00:56:42
User entered 'sore throat and FEVER' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Jan 2021 00:56:15
User opened query 'Per DM CLR: Please note that there are no AEs that match this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:41:30
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:41:20
User entered 'pain and fever'	Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '1000'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'mg (mg)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'three times daily (TID)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '18 Nov 2020'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
Signature has been broken.	(b) (4)	
	Ashley Bragg (b) (4)	09 Mar 2021 22:54:14
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Ashley Bragg (b) (4)	09 Mar 2021 22:54:14
User signature succeeded.	(b) (4)	
	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4)	
	Ashley Bragg (b) (4)	04 Dec 2020 23:25:54
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
Signature has been broken.	(b) (4)	
	Ashley Bragg (b) (4)	09 Mar 2021 22:54:14
	(b) (4)	
User entered '29 Nov 2020' reason for change: New Information	Ashley Bragg (b) (4)	09 Mar 2021 22:54:14
User signature succeeded.	(b) (4)	
	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	04 Dec 2020 23:25:54
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User entered '3'	System	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User entered '1'	System	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:27
User entered '804 (804)'	System	04 Dec 2020 23:25:54

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
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) (b) (4)	09 Mar 2021 22:56:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 22:56:41
Data point term sent to Coder Coding entries removed.	System Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:56:03 09 Mar 2021 22:55:38
User signature succeeded.	James Peterson (b) (4) (b) (4)	23 Feb 2021 13:31:25
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) (b) (4)	30 Jan 2021 00:58:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 00:58:34
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	30 Jan 2021 00:57:27 30 Jan 2021 00:57:12
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) (b) (4)	04 Dec 2020 23:28:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Dec 2020 23:28:02
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	04 Dec 2020 23:27:18
User entered 'Ibuprofen'	Ashley Bragg (b) (4)	04 Dec 2020 23:27:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
Signature has been broken.	(b) (4) Ashley Bragg (b) (4)	09 Mar 2021 22:55:38
User entered 'COVID-LIKE ILLNESS' reason for change: New Information	(b) (4) Ashley Bragg (b) (4)	09 Mar 2021 22:55:38
User signature succeeded.	(b) (4) James Peterson (b) (4)	23 Feb 2021 13:31:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 05:14:20
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:14:15
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'see sx log taken for sore throat EVENT NAME UPDATED ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 00:57:21
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'see sx log taken for sore throat EVENT NAME UPDATED ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 00:57:17
User entered 'SORE THROAT' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Jan 2021 00:57:12
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:37:09

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:36:56
User entered 'pain'	Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '600'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'mg (mg)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'three times daily (TID)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '19 Nov 2020'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
Signature has been broken.	(b) (4)	
	Ashley Bragg (b) (4)	09 Mar 2021 22:55:38
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Ashley Bragg (b) (4)	09 Mar 2021 22:55:38
User signature succeeded.	(b) (4)	
	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4)	
	Ashley Bragg (b) (4)	04 Dec 2020 23:27:01
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
Signature has been broken.	(b) (4)	
	Ashley Bragg (b) (4)	09 Mar 2021 22:55:38
	(b) (4)	
User entered '29 Nov 2020' reason for change: New Information	Ashley Bragg (b) (4)	09 Mar 2021 22:55:38
User signature succeeded.	(b) (4)	
	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Ashley Bragg (b) (4)	04 Dec 2020 23:27:01
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User entered '3'	System	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User entered '1'	System	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:33
User entered '804 (804)'	System	04 Dec 2020 23:27:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Mar 2021 12:04:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	10 Mar 2021 12:04:49
Data point term sent to Coder	System	09 Mar 2021 22:57:04
Coding entries removed.	Ashley Bragg (b) (4)	09 Mar 2021 22:56:16
User signature succeeded.	(b) (4)	
	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\202003.	(b) (4)	
	Coder Import (b) (4)	02 Feb 2021 08:18:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	02 Feb 2021 08:18:53
Coding entries removed.	System	01 Feb 2021 19:58:12
	(b) (4), (b) (6)	01 Feb 2021 19:57:20
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 05:15:17
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification.' answered with 'CONFIRMED NOT TAKNE FOR A WORSENING' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 00:59:48

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:36:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 23:29:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	04 Dec 2020 23:29:05
User entered 'Clonazepam'	(b) (4)	
	System	04 Dec 2020 23:28:18
	Ashley Bragg (b) (4)	04 Dec 2020 23:28:01
	(b) (4)	

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 05:45:08
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'AE ADDED FOR COVID LIKE ILLNESS' (Site from DM).	Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:56:31
Signature has been broken.	Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:56:16
User entered 'COVID-LIKE ILLNESS' reason for change: New Information	Ashley Bragg (b) (4) (b) (4)	09 Mar 2021 22:56:16
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 03:27:41
User signature succeeded.	James Peterson (b) (4) (b) (4)	23 Feb 2021 13:31:25
User entered 'SHORTNESS OF BREATH' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 19:57:20
User entered 'anxiety'	Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0.25'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'mg (mg)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'once (ONCE)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (ORAL)'	Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '21 Nov 2020'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '21 Nov 2020'	Ashley Bragg (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) Ashley Bragg (b) (4) (b) (4)	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User entered empty.	System	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User entered empty.	System	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:41
User entered empty.	System	04 Dec 2020 23:28:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Jan 2021 15:57:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 15:57:03
Data point term sent to Coder	System	27 Jan 2021 15:56:20
User entered 'Mirena'	Bradley Young (b) (4) (b) (4) (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Yes (Y)'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'pregnancy prophylaxis'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '20'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'ug (ug)'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'other (OTHER)'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'continuous'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Other (OTHER)'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'intrauterine'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '9 Nov 2020'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '0'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered 'Yes (Y)'	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered empty.	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 16:01:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 16:01:15
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bragg (b) (4)	01 Feb 2021 16:01:15
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 15:55:31
User entered empty.	Bradley Young (b) (4)	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 15:55:31

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 16:08:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	16 Mar 2021 16:08:29
Coding entries removed.	(b) (4), (b) (6)	16 Mar 2021 16:07:57
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jan 2021 00:49:31
Data point term sent to Coder	(b) (4)	
User entered 'LACTATED RINGERS'	System	30 Jan 2021 00:49:23
	(b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User closed query 'Per DM CLR: Please update the indication to reflect the type of surgical procedure. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 05:53:23
Query 'Per DM CLR: Please update the indication to reflect the type of surgical procedure. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:08:05
Signature has been broken.		16 Mar 2021 16:07:57
User entered 'cholecystectomy SURGICAL PROPHYLAXIS' reason for change: Data Entry Error		16 Mar 2021 16:07:57
User opened query 'Per DM CLR: Please update the indication to reflect the type of surgical procedure. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM).		05 Mar 2021 03:29:00
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'SURGICAL PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '600'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User entered empty.	System	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User entered empty.	System	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:59
User entered empty.	System	30 Jan 2021 00:48:56

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Jan 2021 00:50:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 00:50:30
Data point term sent to Coder	System	30 Jan 2021 00:50:24
User entered 'OMEPRAZOLE'	(b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'GASTRO ESOPHAGEAL REFLUX DISEASE'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '20'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Jan 2021 00:50:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Jan 2021 00:51:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Jan 2021 00:51:26
Data point term sent to Coder	System	30 Jan 2021 00:51:25
User entered 'ZOFRAN'	(b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'NAUSEA PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '4'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '01 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User entered empty.	System	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User entered empty.	System	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:41:11
User entered empty.	System	30 Jan 2021 00:51:04

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:29:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:29:55
Data point term sent to Coder Coding entries removed.	System	25 Mar 2021 18:35:07
	Kenadie Hamblin (b) (4)	25 Mar 2021 18:34:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 12:11:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 12:11:59
Data point term sent to Coder	System	09 Mar 2021 20:50:43
User entered 'HYDROMORPHONE'	(b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User closed query 'Per DM CLR: This Conmed is given for the AE#2 BILIARY DYSKINESIA. However, the "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 05:49:40
Query 'Per DM CLR: This Conmed is given for the AE#2 BILIARY DYSKINESIA. However, the "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'Info corrected on AE eCRF. ' (Site from DM).	Kenadie Hamblin (b) (4)	07 Apr 2021 15:02:02
User opened query 'Per DM CLR: This Conmed is given for the AE#2 BILIARY DYSKINESIA. However, the "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 17:05:18
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'BILIARY DISKINESIA'	(b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '0.5'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 06:58:48
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'Updated. ' (Site from DM).	Kenadie Hamblin (b) (4) (b) (4)	25 Mar 2021 18:42:30
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Kenadie Hamblin (b) (4) (b) (4)	25 Mar 2021 18:34:39
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 02:29:06
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User entered empty.	System	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User entered empty.	System	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:41
User entered empty.	System	09 Mar 2021 20:49:46

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Mar 2021 20:52:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 20:52:40
Data point term sent to Coder	System	09 Mar 2021 20:51:44
User entered 'ZOFRAN'	(b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'NAUSEA PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '4'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User signature succeeded.	James Peterson (b) (4)	03 Apr 2021 00:09:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User entered empty.	System	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User entered empty.	System	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:10:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:40:49
User entered empty.	System	09 Mar 2021 20:51:01

US3332034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:10:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:40:25
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:16:06

US3332034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:35

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:16:42

US3332034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'LAPAROSCOPIC CHOLECYSTECTOMY'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:16:42

US3332034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:16:42

US3332034

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:35

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:16:42

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered		
'USA-US202-2021-MRNA-1273-P301000001'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'No (N)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'Yes (Y)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'James'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Peterson'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'US'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 20:00:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '3'	System	01 Feb 2021 20:17:44
User entered '2'	System	15 Jan 2021 16:17:50
User entered '1'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered		
'USA-US202-2021-MRNA-1273-P301000001'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'No (N)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'Yes (Y)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'James'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Peterson'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'US'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 20:00:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '3'	System	01 Feb 2021 20:17:44
User entered '2'	System	15 Jan 2021 16:17:50
User entered '1'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:34:07
User entered '05/Jan/2021 15:50'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:35

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.

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.		05 Jan 2021 20:51:03
User entered '1'		05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered		
'USA-US202-2021-MRNA-1273-P301000001'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'No (N)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'Yes (Y)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'James'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Peterson'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'US'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 20:00:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '3'	System	01 Feb 2021 20:17:44
User entered '2'	System	15 Jan 2021 16:17:50
User entered '1'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '15/Jan/2021 16:17'	(b) (4) System	15 Jan 2021 16:17:50

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:35

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.

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:17:23
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 16:17:50

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered		
'USA-US202-2021-MRNA-1273-P301000001'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'No (N)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'Yes (Y)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'James'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Peterson'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'US'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 20:00:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '3'	System	01 Feb 2021 20:17:44
User entered '2'	System	15 Jan 2021 16:17:50
User entered '1'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered '01/Feb/2021 15:17'	(b) (4) System	01 Feb 2021 20:17:44

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:35

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.

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:17:44

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered		
'USA-US202-2021-MRNA-1273-P301000001'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

Serious

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'No (N)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Yes (Y)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 20:17:23
Un-reviewed for Safety.	System	30 Jan 2021 00:39:12
DataPoint Un-verified.	System	30 Jan 2021 00:39:12
User entered 'Yes (Y)'	System	30 Jan 2021 00:39:12
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'No (N)'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'James'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'Peterson'	System	05 Jan 2021 20:50:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:34:07
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 20:51:03
User entered 'US'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	07 Apr 2021 20:00:43
User signature succeeded.	James Peterson (b) (4)	23 Feb 2021 13:31:25
	(b) (4)	
User entered '3'	System	01 Feb 2021 20:17:44
User entered '2'	System	15 Jan 2021 16:17:50
User entered '1'	System	05 Jan 2021 20:50:59

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:07
User entered '07/Apr/2021 13:00'	(b) (4) System	07 Apr 2021 20:00:43

US3332034

Folder: SAE USA-US202-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:35

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.

Audit	User	Time (GMT)
User signature succeeded.	James Peterson (b) (4)	12 Apr 2021 16:04:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 20:00:43