

US3662033 (Prod: Cincinnati CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:21:09

All time stamps listed in this document are displayed in GMT

US3662033

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 14:56:37

Generated On: 10 Jun 2021 09:21:09

Participant ID

US3662033

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

US3662033

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:18:12

Generated On: 10 Jun 2021 09:21:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
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) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Date of Informed Consent (<i>dd MMM yyyy</i>)	01 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Mar 2021 21:18:08

Generated On: 10 Jun 2021 09:21:09

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Condition	UNSPECIFIED VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	23 APR 2019
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)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3662033

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	01 JAN 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Condition	GENERALIZED JOINT PAIN
Start date (dd MMM yyyy)	01 JAN 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3662033

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Condition	ANXIETY STATE, UNSPECIFIED
Start date (dd MMM yyyy)	01 JAN 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Condition	PAROXYSMAL ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	01 JAN 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: Medical History (6)

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Condition	HYPERTENSION NEC
Start date (dd MMM yyyy)	01 JAN 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: Medical History (7)

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Condition	OTHER AND UNSPECIFIED OSTEOARTHRITIS
Start date (dd MMM yyyy)	01 JAN 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	1 JUL 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)	JUL 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3662033

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:18:12

Generated On: 10 Jun 2021 09:21:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:30
Height (<i>xxx.x</i>)	64 in
Weight (<i>xxx.x</i>)	94.7 kg
BMI (<i>xxx.x</i>)	35.83625 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:08

Generated On: 10 Jun 2021 09:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Date of assessment (dd MMM yyyy) 01 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) 01 JAN 2005

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Mar 2021 21:18:08

Generated On: 10 Jun 2021 09:21:09

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) 18 Mar 2021 21:18:08

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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) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 188604

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) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

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) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

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)	01 SEP 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 09:30
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

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)	01 SEP 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 10:55
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

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: Exposure

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

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) 1 SEP 2020

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

Treatment Date and Time (derived) 1 SEP 2020 10:24

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) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 SEP 2020
Collection time (00:00-23:59)	10:10 (24 HR)
Collection date and time (derived)	01 SEP 2020 10:10

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:00	01 SEP 2020 10:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

01 SEP 2020 10:58

PC Open Date & Time

01 SEP 2020 10:44

PC Close Date & Time

01 SEP 2020 13:14

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °F

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

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

PC Time Stamp	01 SEP 2020 19:07
PC Open Date & Time	01 SEP 2020 14:09
PC Close Date & Time	02 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	02 SEP 2020 18:43
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

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

95.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 19:22

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

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

98.1 °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 18:25

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

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

98.1 °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

06 SEP 2020 18:58

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

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

07 SEP 2020 20:28

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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

01 SEP 2020 10:59

PC Open Date & Time

01 SEP 2020 10:44

PC Close Date & Time

01 SEP 2020 13:14

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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

01 SEP 2020 19:08

PC Open Date & Time

01 SEP 2020 14:09

PC Close Date & Time

02 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

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

02 SEP 2020 18:43

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

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

03 SEP 2020 20:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

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

04 SEP 2020 19:22

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

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

05 SEP 2020 18:25

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

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

06 SEP 2020 18:58

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

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

07 SEP 2020 20:28

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 10:59
PC Open Date & Time	01 SEP 2020 10:44
PC Close Date & Time	01 SEP 2020 13:14

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 19:08
PC Open Date & Time	01 SEP 2020 14:09
PC Close Date & Time	02 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

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 ☒

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 18:44
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

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)

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:37
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

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 3384

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:23
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

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 ☒

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:26
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

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

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EAB) (1725)

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:59
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

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 ☒

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 20:29
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3662033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 08:20
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:55
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3662033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 SEP 2020

What was the treatment time? (00:00-23:59) 09:24 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 09:24

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

US3662033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

08:45 (24 HR)

Collection date and time (derived)

29 SEP 2020 08:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:40	29 SEP 2020 08:40
Nasopharyngeal Swab 2	No		

US3662033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

29 SEP 2020 09:56

PC Open Date & Time

29 SEP 2020 09:44

PC Close Date & Time

29 SEP 2020 12:14

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 29 SEP 2020 19:03

PC Open Date & Time 29 SEP 2020 13:09

PC Close Date & Time 30 SEP 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 30 SEP 2020 18:24

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

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

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 18:23

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 19:29

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

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 99.3 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 03 OCT 2020 19:09

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

05 OCT 2020 08:58

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

05 OCT 2020 18:59

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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

29 SEP 2020 09:57

PC Open Date & Time

29 SEP 2020 09:44

PC Close Date & Time

29 SEP 2020 12:14

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 19:04

PC Open Date & Time

29 SEP 2020 13:09

PC Close Date & Time

30 SEP 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 18:25

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

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

01 OCT 2020 18:23

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

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

02 OCT 2020 19:29

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 19:10

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

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

05 OCT 2020 08:58

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

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

05 OCT 2020 19:00

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 09:58
PC Open Date & Time	29 SEP 2020 09:44
PC Close Date & Time	29 SEP 2020 12:14

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 19:05
PC Open Date & Time	29 SEP 2020 13:09
PC Close Date & Time	30 SEP 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

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 ☒

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 18:25
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

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 ☒

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 18:24
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

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 ☒

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 19:30
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

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)

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:10
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

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 ☒

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 08:58
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

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 ☒

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:00
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3662033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 12:04
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3662033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

12:05 (24 HR)

Collection date and time (derived)

28 OCT 2020 12:05

US3662033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:13

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 07:17:10
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

15 NOV 2020 08:22:05

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 21:31:33

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 89

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

No ☒

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 NOV 2020 12:01:04

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 12:00:47
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 12 DEC 2020 10:42:41

Patient Cloud Open Date & Time 10 DEC 2020 00:01

Patient Cloud Close Date & Time 14 DEC 2020 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 12:29:39
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

26 DEC 2020 08:56:55

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 12:01:31
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 09:05:42
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 JAN 2021 12:03:25
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

23 JAN 2021 12:02:58

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

28 JAN 2021 10:19:42

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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	04 FEB 2021 10:45:03
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 11:11:39

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

18 FEB 2021 10:29:35

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

25 FEB 2021 17:18:42

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 22:32:06

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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	13 MAR 2021 10:47:29
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

20 MAR 2021 13:06:09

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

27 MAR 2021 12:00:38

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

02 APR 2021 19:44:11

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

09 APR 2021 11:59:33

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

15 APR 2021 06:12:41

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 11:30:02

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

29 APR 2021 06:13:25

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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="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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	08 NOV 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

Patient Cloud Open Date & Time	18 NOV 2021 00:01
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Patient Cloud Close Date & Time	22 NOV 2021 23:59
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US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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°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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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="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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 <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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐
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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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Patient Cloud Close Date & Time	26 SEP 2022 23:59
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US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3662033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:21:09

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		04 MAR 2021 22:32:20

US3662033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:47:48

Generated On: 10 Jun 2021 09:21:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:47:48

Generated On: 10 Jun 2021 09:21:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 APR 2021
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	6 APR 2021 12:43
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:47:48

Generated On: 10 Jun 2021 09:21:09

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.

US3662033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:47:48

Generated On: 10 Jun 2021 09:21:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 APR 2021
Collection time (00:00-23:59)	12:53 (24 HR)
Collection date and time (derived)	6 APR 2021 12:53

US3662033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:47:48

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3662033

Folder: Covid-19 Assessment (2)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Date of Contact	17 OCT 2020
Time of Contact	17:00
Date and Time of Contact (derived)	17 OCT 2020 17:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Form: Symptom Log (5)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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 17 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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 17 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 OCT 2020	
Assessment Not Done	False	
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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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 17 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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 17 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 OCT 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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 (11)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 OCT 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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"/>

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Symptom Day

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Date of Visit	19 OCT 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	19 OCT 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

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

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

Visit date (dd MMM yyyy)	19 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	SICKD1
------------	--------

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 09:22
Height (xxx.x)	162.6 cm
Weight (xxx.x)	90.6 kg
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3662033

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

US3662033

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

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

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

Visit date (dd MMM yyyy)	12 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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US3662033

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3662033

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Height	162.56 cm
Weight	97.34 kg
BMI (xxx.x)	36.83528

US3662033

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Height	162.56 cm
Weight	97.34 kg
BMI (xxx.x)	36.83528
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 13:13
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3662033

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Height	162.56 cm
Weight	97.34 kg
BMI (xxx.x)	36.83528
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 14:17
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3662033

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

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3662033

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

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 13:51 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 13:51

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

What was the frequency of the study treatment dosing? ONCE

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

US3662033

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	13:25 (24 HR)
Collection date and time (derived)	12 JAN 2021 13:25

US3662033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	13:20
Collection Date and Time (derived)	12 JAN 2021 13:20

US3662033

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

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

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 FEB 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 09:10
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

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)	10 FEB 2021
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 10:01
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3662033

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3662033

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

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) 10 FEB 2021

What was the treatment time? (00:00-23:59) 09:31 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 09:31

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

US3662033

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662033

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:07

Generated On: 10 Jun 2021 09:21:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662033

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:08 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 09:08
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662033

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

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.

US3662033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00-23:59)	09:12 (24 HR)
Collection date and time (derived)	9 MAR 2021 09:12

US3662033

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 14:56:38

Generated On: 10 Jun 2021 09:21:09

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID	USA-US088-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE APPENDICITIS
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)	8 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	True
Hospital Admission Date (dd MMM yyyy)	8 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	10 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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	

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

PT IS A 67YO FEMALE, H/O
ATRIAL FIB (ELIQUIS - LAST
DOSE TUES AM), PRESENTS
WITH ACUTE RLQ ABDOMINAL
PAIN X2 DAYS. LOW GRADE
FEVER. +NAUSEA. EXAM AND
CT C/W ACUTE APPENDICITIS

ACUTE APPENDICITIS - PLAN
OR FOR LAP APPY BUT GIVEN
THERAPEUTIC ON ELIQUIS
WILL PLAN FOR OR LIKELY
END OF DAY WEDNESDAY.
INFORMED CONSENT
OBTAINED AFTER ALL
RISKS/BENEFITS DISCUSSED
INCLUDING RISK OF BLEEDING
AND CONVERSION TO OPEN. IV
ABX, NPO, ADMIT TO FLOOR.
PARTICIPANT STILL IN ER, HAS
NOT BEEN ADMITTED AT THIS
TIME.

LAPAROSCOPIC
APPENDECTOMY PERFORMED
9/9/2020. UNCOMPLICATED.
PATHOLOGY: FINAL
DIAGNOSIS:

APPENDIX, APPENDECTOMY:
- SEVERE ACUTE APPENDICITIS
WITH ACUTE SEROSITIS.
- NEGATIVE FOR
MALIGNANCY.

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)	0

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID

Adverse event

ABDOMINAL PAIN POST-OP

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)

11 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID	USA-US088-2020-MRNA-1273-P30 1000001
Adverse event	ABDOMINAL PAIN
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)	08 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	10 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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	
PARTICIPANT DIAGNOSED WITH ACUTE APPENDICITIS. SAE COMPLETED FOR ACUTE APPENDICITIS	
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)	0
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID

Adverse event

ABDOMINAL PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID	
Adverse event	LOW GRADE FEVER 100.4
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	07 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 SEP 2020
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 (5)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID

Adverse event

FATIGUE, POST SURGICAL

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)

10 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID

Adverse event

MUSCLE ACHES,
DISSEMINATED

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)

03 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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 type="radio"/> Related <input checked="" 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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID

Adverse event

MUSCLE ACHES,
DISSEMINATED

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)

29 SEP 2020

Start time (00:00-23:59)

19:05 (24 HR)

AE start date and time (derived)

29 SEP 2020 19:05

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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 type="radio"/> Related <input checked="" 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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID

Adverse event

SINUS CONGESTION

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)

08 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

AEID

Adverse event

POST NASAL DRIP

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)

08 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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:	
<hr/>	
Narrative	
<hr/>	
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 (11)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (12)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 14:56:39

Generated On: 10 Jun 2021 09:21:09

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) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication STIOLO RESPIMAT (MIST)

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 2.5

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 (1)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" 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)	01 JUL 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication FLECAINIDE ACETATE

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL ATRIAL
FIBRILLATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 22:53:45

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 MAY 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

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 (3)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)	23 APR 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL ATRIAL
FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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 AUG 2017
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
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) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 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 (5)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 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 (6)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 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 (6)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 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)	2	
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 (7)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 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 (7)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 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 (8)

Data signed: (b) (4) 29 Apr 2021 22:53:45

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Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED JOINT PAIN

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 (8)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		02 SEP 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 (9)

Data signed: (b) (4) 29 Apr 2021 22:53:45

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Name of Medication CEFUROXIME

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication OXYCODONE HCI

Prophylaxis Yes ☐
No ☒

Indication POST-OP ABDOMINAL PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication PIPERACILLIN SODIUM

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 3.375

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 (11)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication CEFTRIAXONE SODIUM

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN

Dose per administration 15

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 (13)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication POST OP ABDOMINAL PAIN

Dose per administration 12.5

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) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication PRE-OP

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 (16)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 22:53:45

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Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication PRE-OP

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 (17)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COPD

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN

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 (19)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication ALIGN PROBIOTIC

Prophylaxis Yes ☒
No ☐

Indication DIGESTIVE SUPPORT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication SENNA CONCENTRATE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES

Dose per administration 650

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 (22)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 03 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES

Dose per administration 650

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 (23)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FEVER/ABDOMINAL PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SINUS CONGESTION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication OMNIPAQUE 350MG/ML

Prophylaxis Yes ☐
No ☒

Indication CT CONTRAST/PROCEDURE

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		8 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 8 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SPASM OF LOWER
BACK

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		19 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

Name of Medication ROBAXIN

Prophylaxis Yes ☒
No ☐

Indication MUSCLE SPASM OF LOWER
BACK

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 22:53:45

Generated On: 10 Jun 2021 09:21:09

	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)		19 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 18 Mar 2021 21:18:05

Generated On: 10 Jun 2021 09:21:09

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 SEP 2020	LAPAROSCOPIC APPENDECTOMY	Adverse Event	
08 SEP 2020	CT ABDOMEN AND PELVIS WITH CONTRAST	Adverse Event	

US3662033

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:21:09

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

US3662033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:21:09

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 ☐

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

SAEID	USA-US088-2020-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 checked="" type="radio"/> No <input 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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

SAEID	USA-US088-2020-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 checked="" type="radio"/> No <input 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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/SEP/2020 20:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

SAEID	USA-US088-2020-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 checked="" type="radio"/> No <input 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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 18:12
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

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

SAEID	USA-US088-2020-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 checked="" type="radio"/> No <input 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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/OCT/2020 15:55
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

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

SAEID	USA-US088-2020-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 checked="" type="radio"/> No <input 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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/OCT/2020 13:01
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

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 18 Mar 2021 21:18:06

Generated On: 10 Jun 2021 09:21:09

SAEID	USA-US088-2020-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 checked="" type="radio"/> No <input 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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/OCT/2020 14:42
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

US3662033 (Prod: Cincinnati CRS)

US3662033

Form: Participant Creation

Generated On: 10 Jun 2021 09:21:09

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'US3662033'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:35:13

US3662033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:53:52

US3662033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:35:14

US3662033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:53:52

US3662033

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'SCRN'	System	01 Sep 2020 13:53:52

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:35:15

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Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '67'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'YEARS'	System	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '67'	System	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:21:09

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:54:46

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Sep 2020'	System	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '2020'	System	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:55:15

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:35:14

US3662033

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:21:09

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'I'	System	01 Sep 2020 13:55:26

US3662033

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:21:09

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 13:55:26

US3662033

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:21:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:06:35

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Unspecified vitamin D deficiency - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Sep 2020 20:08:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 20:08:53
Data point term sent to Coder	System	02 Sep 2020 20:08:07
User entered 'Unspecified Vitamin D Deficiency'	Brenda Miller (b) (4)	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '23 Apr 2019'	Brenda Miller (b) (4)	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Apr 2019'	System	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '2019'	System	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:21:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:07:24

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User closed query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:44:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:15:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 19:15:40
Data point term sent to Coder	System	28 Sep 2020 19:14:19
Query 'Per MM, please expand the abbreviation ' answered with 'Corrected data' (Site from DM).	Brenda Miller (b) (4) (b) (4)	28 Sep 2020 19:14:10
Coding entries removed.	Brenda Miller (b) (4) (b) (4)	28 Sep 2020 19:13:55
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	28 Sep 2020 19:13:55
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:23:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 13:33:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 13:33:38
Data point term sent to Coder	System	04 Sep 2020 13:32:27
User entered 'COPD' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	04 Sep 2020 13:31:58
Data point term sent to Coder	System	02 Sep 2020 20:11:15
User entered 'Obstructive Chronic Bronchitis without Acute Exacerbation'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Jan 2019'	Brenda Miller (b) (4)	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Jan 2019'	System	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '2019'	System	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:21:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:10:17

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Joint Pain (wrists, hips, knees, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 09:27:09
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:04:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 18:04:39
Data point term sent to Coder	System	27 Oct 2020 18:04:18
Query 'Per DM CLR: Please update the condition to include the type and/or location of Joint Pain (wrists, hips, knees, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 18:03:44
' answered with 'CORRECTED DATA' (Site from DM).		
Coding entries removed.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 18:03:34
User entered 'GENERALIZED JOINT PAIN' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 18:03:34
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Joint Pain (wrists, hips, knees, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	26 Oct 2020 04:40:09
' (Site from DM).		

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:11:46
Data point term sent to Coder	System	02 Sep 2020 20:11:15
User entered 'Joint Pain'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Jan 2019'	Brenda Miller (b) (4)	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Jan 2019'	System	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '2019'	System	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:21:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:10:42

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety state, unspecified - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Sep 2020 20:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:11:46
Data point term sent to Coder	System	02 Sep 2020 20:11:16
User entered 'Anxiety State, Unspecified'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Jan 2016'	Brenda Miller (b) (4)	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Jan 2016'	System	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '2016'	System	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:21:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:11:10

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Sep 2020 18:43:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Sep 2020 18:43:49
Data point term sent to Coder	System	20 Sep 2020 18:42:58
User entered 'Paroxysmal atrial fibrillation'	michelle saemann (b) (4)	20 Sep 2020 18:42:21
	(b) (4)	

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Jan 2010'	(b) (4) michelle saemann (b) (4)	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) michelle saemann (b) (4)	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) michelle saemann (b) (4)	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) michelle saemann (b) (4)	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Jan 2010'	System	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '2010'	System	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:21:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	20 Sep 2020 18:42:21

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	02 Sep 2020 20:15:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:15:55
Data point term sent to Coder	System	02 Sep 2020 20:14:27
User entered 'Hypertension NEC'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Jan 2010'	Brenda Miller (b) (4)	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Jan 2010'	System	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '2010'	System	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:21:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:14:25

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 13:23:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 13:23:40
Data point term sent to Coder	System	02 Sep 2020 20:15:29
User entered 'Other and Unspecified Osteoarthritis'	Brenda Miller (b) (4)	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Jan 1990'	Brenda Miller (b) (4)	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Jan 1990'	System	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '1990'	System	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:21:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	02 Sep 2020 20:15:20

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Oct 2020 16:18:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 16:18:27
Data point term sent to Coder	System	17 Oct 2020 16:18:02
User entered 'post menopausal'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '1 Jul 2005'	(b) (4) michelle saemann (b) (4)	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) michelle saemann (b) (4)	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) michelle saemann (b) (4)	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) michelle saemann (b) (4)	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'Jul 2005'	System	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '2005'	System	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:21:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered empty.	System	17 Oct 2020 16:17:21

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '01 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '09:30'	(b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '01 Sep 2020 09:30'	System	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '64' in	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:00
DataPoint set to visible.	System	01 Sep 2020 13:55:26

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '94.7' kg	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:00
DataPoint set to visible.	System	01 Sep 2020 13:55:26

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered '35.83625'	System	01 Sep 2020 14:01:00
DataPoint set to visible.	System	01 Sep 2020 13:55:26

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'kg/m2'	System	01 Sep 2020 14:01:00
DataPoint set to visible.	System	01 Sep 2020 13:55:26

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 20:05:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 20:05:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Miller (b) (4)	02 Sep 2020 20:05:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	01 Sep 2020 14:01:00
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 20:05:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 20:05:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Miller (b) (4)	02 Sep 2020 20:05:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	01 Sep 2020 14:01:00
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'bpm'	System	02 Sep 2020 20:05:30
User entered empty.	System	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 20:05:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 20:05:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Miller (b) (4)	02 Sep 2020 20:05:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	01 Sep 2020 14:01:00
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'breaths/min'	System	02 Sep 2020 20:05:30
User entered empty.	System	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 20:05:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 20:05:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Miller (b) (4)	02 Sep 2020 20:05:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	01 Sep 2020 14:01:00
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'mmHg'	System	02 Sep 2020 20:05:30
User entered empty.	System	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 20:05:30
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 20:05:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Miller (b) (4)	02 Sep 2020 20:05:30
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	01 Sep 2020 14:01:00
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:01:00

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User entered 'mmHg'	System	02 Sep 2020 20:05:30
User entered empty.	System	01 Sep 2020 14:01:00

US3662033

Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	04 Sep 2020 13:31:15

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Sep 2020'	Brenda Miller (b) (4)	04 Sep 2020 13:31:15

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:58:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:09

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:58:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:09

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User closed query 'Per CDM Re-Query: Post-Menopausal is considered part of the patient medical history. Please add. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:55:04
Query 'Per CDM Re-Query: Post-Menopausal is considered part of the patient medical history. Please add. Thank you' answered with 'done' (Site from DM).	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:16:52
User opened query 'Per CDM Re-Query: Post-Menopausal is considered part of the patient medical history. Please add. Thank you' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:50:10
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:50:10
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'NCS, PER PI' (Site from DM).	Brenda Miller (b) (4) (b) (4)	12 Oct 2020 12:54:49
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 23:06:24
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	01 Sep 2020 13:58:21

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Folder: Screening

Form: Childbearing Potential

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[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:58:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:58:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:09

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:58:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '01 Jan 2005'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:58:21

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:21:09

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:58:21

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

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[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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

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[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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

US3662033

Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

US3662033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
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	01 Sep 2020 13:59:16
User entered 'No (N)' reason for change: Data Entry Error	System	01 Sep 2020 13:59:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 13:59:16
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

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[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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

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)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

US3662033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

US3662033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 13:59:03

US3662033

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:21:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:20:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:59:03

US3662033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:18:50

US3662033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '01 Sep 2020'	Brenda Miller (b) (4)	02 Sep 2020 20:18:50

US3662033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	02 Sep 2020 20:18:50

US3662033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'VISIT1'	System	02 Sep 2020 20:18:50

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:54:35

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '188604'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:54:35

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:54:35

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

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)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:57:18

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

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)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:57:18

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:57:18

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:57:18

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:57:18

US3662033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:21:09

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 23:14:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:52:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:52:54

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '01 Sep 2020'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '09:30'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '01 Sep 2020 09:30'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '97.5' F	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Oral (Oral)'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '59'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'bpm'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '16'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'breaths/min'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '148'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '70'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '01 Sep 2020'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '10:55'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '01 Sep 2020 10:55'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '97.8' F	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Oral (Oral)'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '62'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'bpm'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 13:34:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	04 Sep 2020 13:34:21
User entered '16' reason for change: New Information	Brenda Miller (b) (4)	04 Sep 2020 13:34:21
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Sep 2020 20:22:15
User entered empty.	System	02 Sep 2020 20:22:15
	Brenda Miller (b) (4)	02 Sep 2020 20:22:15
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'breaths/min'	System	04 Sep 2020 13:34:21
User entered empty.	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '154'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '93'	Brenda Miller (b) (4)	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	02 Sep 2020 20:22:15

US3662033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	Brenda Miller (b) (4)	02 Sep 2020 20:24:22

US3662033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:24:22

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

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)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '1 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '10:24'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '1 Sep 2020 10:24'	System	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'ONCE'	System	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 14:33:09

US3662033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:25:29

US3662033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '01 Sep 2020'	Brenda Miller (b) (4)	02 Sep 2020 20:25:29

US3662033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '10:10'	Brenda Miller (b) (4)	02 Sep 2020 20:25:29

US3662033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '01 Sep 2020 10:10'	System	02 Sep 2020 20:25:29

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '01 Sep 2020'	Brenda Miller (b) (4)	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '10:00'	Brenda Miller (b) (4)	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '01 Sep 2020 10:00'	System	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	Brenda Miller (b) (4)	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	Brenda Miller (b) (4)	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered empty.	System	04 Sep 2020 13:38:53

US3662033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:28:07

US3662033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	02 Sep 2020 20:28:07

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:58:25', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd3918c67-fbfe-4ec3-9536-cfbef2dfdc64'	System	01 Sep 2020 14:58:53
User entered 'Yes (Y)'	System	01 Sep 2020 14:58:53

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:58:34', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd3918c67-fbfe-4ec3-9536-cfbef2dfdc64' User entered '97.8'	System	01 Sep 2020 14:58:53
	System	01 Sep 2020 14:58:53

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:58:45', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd3918c67-fbfe-4ec3-9536-cfbef2dfdc64'	System	01 Sep 2020 14:58:53
User entered 'No (N)'	System	01 Sep 2020 14:58:53

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:58:50', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd3918c67-fbfe-4ec3-9536-cfbef2dfdc64' User entered '01 Sep 2020 10:58'	System	01 Sep 2020 14:58:53
	System	01 Sep 2020 14:58:53

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 10:44'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 13:14'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:06:49', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd6012cbd-90ad-4c4e-a7bb-8228e161cdd0' User entered 'Yes (Y)'	System	01 Sep 2020 23:07:37
	System	01 Sep 2020 23:07:37

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:07:11', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd6012cbd-90ad-4c4e-a7bb-8228e161cdd0' User entered '97.0'	System	01 Sep 2020 23:07:37
	System	01 Sep 2020 23:07:37

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:07:17', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd6012cbd-90ad-4c4e-a7bb-8228e161cdd0' User entered 'No (N)'	System	01 Sep 2020 23:07:37
	System	01 Sep 2020 23:07:37

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:07:36', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd6012cbd-90ad-4c4e-a7bb-8228e161cdd0' User entered '01 Sep 2020 19:07'	System	01 Sep 2020 23:07:37
	System	01 Sep 2020 23:07:37

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 14:09'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 2'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:42:57', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a2ceec2f-c6fc-4ed9-97c1-ae9a0cd64064' User entered 'Yes (Y)'	System	02 Sep 2020 22:43:34
	System	02 Sep 2020 22:43:34

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:05', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a2ceec2f-c6fc-4ed9-97c1-ae9a0cd64064' User entered '97.9'	System	02 Sep 2020 22:43:34
	System	02 Sep 2020 22:43:34

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:12', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a2ceec2f-c6fc-4ed9-97c1-ae9a0cd64064'	System	02 Sep 2020 22:43:34
User entered 'Yes (Y)'	System	02 Sep 2020 22:43:34

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted and the medication was recorded on med page' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:22:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Brenda Miller (b) (4)	13 Oct 2020 13:57:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a2ceec2f-c6fc-4ed9-97c1-ae9a0cd64064'	(b) (4)	
User entered '1'	System	02 Sep 2020 22:43:34
	System	02 Sep 2020 22:43:34
	System	02 Sep 2020 22:43:34

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a2ceec2f-c6fc-4ed9-97c1-ae9a0cd64064' User entered '0'	System	02 Sep 2020 22:43:34
	System	02 Sep 2020 22:43:34

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a2ceec2f-c6fc-4ed9-97c1-ae9a0cd64064' User entered '02 Sep 2020 18:43'	System	02 Sep 2020 22:43:34
	System	02 Sep 2020 22:43:34

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 3'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:35:51', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '23ab12c5-5cf8-40d4-bf74-1d3324104f30' User entered 'Yes (Y)'	System	04 Sep 2020 00:36:14
	System	04 Sep 2020 00:36:14

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:35:58', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '23ab12c5-5cf8-40d4-bf74-1d3324104f30' User entered '95.1'	System	04 Sep 2020 00:36:14
	System	04 Sep 2020 00:36:14

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:03', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '23ab12c5-5cf8-40d4-bf74-1d3324104f30'	System	04 Sep 2020 00:36:14
User entered 'No (N)'	System	04 Sep 2020 00:36:14

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:10', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '23ab12c5-5cf8-40d4-bf74-1d3324104f30' User entered '03 Sep 2020 20:36'	System	04 Sep 2020 00:36:14
	System	04 Sep 2020 00:36:14

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 4'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:21:53', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '95a45614-68cf-4365-b44f-7efadfdc80a7' User entered 'Yes (Y)'	System	04 Sep 2020 23:22:13
	System	04 Sep 2020 23:22:13

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '95a45614-68cf-4365-b44f-7efadfdc80a7' User entered '98.4'	System	04 Sep 2020 23:22:13
	System	04 Sep 2020 23:22:13

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:05', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '95a45614-68cf-4365-b44f-7efadfdc80a7' User entered 'No (N)'	System	04 Sep 2020 23:22:13
	System	04 Sep 2020 23:22:13

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:11', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '95a45614-68cf-4365-b44f-7efadfdc80a7' User entered '04 Sep 2020 19:22'	System	04 Sep 2020 23:22:13
	System	04 Sep 2020 23:22:13

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 5'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:22', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'def43bc2-7713-4d01-bad8-28e53c6b8a39' User entered 'Yes (Y)'	System	05 Sep 2020 22:25:45
	System	05 Sep 2020 22:25:45

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:28', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'def43bc2-7713-4d01-bad8-28e53c6b8a39' User entered '98.1'	System	05 Sep 2020 22:25:45
	System	05 Sep 2020 22:25:45

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'def43bc2-7713-4d01-bad8-28e53c6b8a39'	System	05 Sep 2020 22:25:45
User entered 'No (N)'	System	05 Sep 2020 22:25:45

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'def43bc2-7713-4d01-bad8-28e53c6b8a39' User entered '05 Sep 2020 18:25'	System	05 Sep 2020 22:25:45
	System	05 Sep 2020 22:25:45

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 6'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:57:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3ac53dba-6886-4f3a-b8ca-df1f190f41d6' User entered 'Yes (Y)'	System	06 Sep 2020 22:58:15
	System	06 Sep 2020 22:58:15

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:57:58', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3ac53dba-6886-4f3a-b8ca-df1f190f41d6' User entered '98.1'	System	06 Sep 2020 22:58:15
	System	06 Sep 2020 22:58:15

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:58:04', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3ac53dba-6886-4f3a-b8ca-df1f190f41d6' User entered 'No (N)'	System	06 Sep 2020 22:58:15
	System	06 Sep 2020 22:58:15

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:58:14', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3ac53dba-6886-4f3a-b8ca-df1f190f41d6' User entered '06 Sep 2020 18:58'	System	06 Sep 2020 22:58:15
	System	06 Sep 2020 22:58:15

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 7'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:27:44', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bd491000-4fc6-4b94-8f69-b440b32d1305' User entered 'Yes (Y)'	System	08 Sep 2020 00:28:04
	System	08 Sep 2020 00:28:04

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:27:51', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bd491000-4fc6-4b94-8f69-b440b32d1305' User entered '98.8'	System	08 Sep 2020 00:28:04
	System	08 Sep 2020 00:28:04

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:27:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bd491000-4fc6-4b94-8f69-b440b32d1305' User entered 'No (N)'	System	08 Sep 2020 00:28:04
	System	08 Sep 2020 00:28:04

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:01', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bd491000-4fc6-4b94-8f69-b440b32d1305' User entered '07 Sep 2020 20:28'	System	08 Sep 2020 00:28:04
	System	08 Sep 2020 00:28:04

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:58:57', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1f0303fd-b63c-40d5-9145-05065cdd9697'	System	01 Sep 2020 14:59:17
User entered 'None (1)'	System	01 Sep 2020 14:59:17

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:01', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1f0303fd-b63c-40d5-9145-05065cdd9697' User entered 'No (N)'	System	01 Sep 2020 14:59:17
	System	01 Sep 2020 14:59:17

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:04', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1f0303fd-b63c-40d5-9145-05065cdd9697' User entered 'No (N)'	System	01 Sep 2020 14:59:17
	System	01 Sep 2020 14:59:17

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:08', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1f0303fd-b63c-40d5-9145-05065cdd9697'	System	01 Sep 2020 14:59:17
User entered 'None (1)'	System	01 Sep 2020 14:59:17

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:14', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1f0303fd-b63c-40d5-9145-05065cdd9697'	System	01 Sep 2020 14:59:17
User entered '01 Sep 2020 10:59'	System	01 Sep 2020 14:59:17

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 10:44'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 13:14'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:07:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'b81e955b-04ad-409e-881c-2554931e2940'	System	01 Sep 2020 23:08:03
User entered 'None (1)'	System	01 Sep 2020 23:08:03

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:07:46', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'b81e955b-04ad-409e-881c-2554931e2940' User entered 'No (N)'	System	01 Sep 2020 23:08:03
	System	01 Sep 2020 23:08:03

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:07:50', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'b81e955b-04ad-409e-881c-2554931e2940' User entered 'No (N)'	System	01 Sep 2020 23:08:03
	System	01 Sep 2020 23:08:03

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:07:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'b81e955b-04ad-409e-881c-2554931e2940'	System	01 Sep 2020 23:08:03
User entered 'None (1)'	System	01 Sep 2020 23:08:03

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:01', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'b81e955b-04ad-409e-881c-2554931e2940'	System	01 Sep 2020 23:08:03
User entered '01 Sep 2020 19:08'	System	01 Sep 2020 23:08:03

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 14:09'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 2'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9ac69bb3-f545-482d-86b6-240e6ad119c1'	System	02 Sep 2020 22:43:58
User entered 'None (1)'	System	02 Sep 2020 22:43:58

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9ac69bb3-f545-482d-86b6-240e6ad119c1' User entered 'No (N)'	System	02 Sep 2020 22:43:58
	System	02 Sep 2020 22:43:58

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:47', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9ac69bb3-f545-482d-86b6-240e6ad119c1' User entered 'No (N)'	System	02 Sep 2020 22:43:58
	System	02 Sep 2020 22:43:58

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9ac69bb3-f545-482d-86b6-240e6ad119c1'	System	02 Sep 2020 22:43:58
User entered 'None (1)'	System	02 Sep 2020 22:43:58

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:43:56', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9ac69bb3-f545-482d-86b6-240e6ad119c1' User entered '02 Sep 2020 18:43'	System	02 Sep 2020 22:43:58
	System	02 Sep 2020 22:43:58

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 3'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:15', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '77fbaab9-4d9a-4277-ba5b-a27689247a07'	System	04 Sep 2020 00:36:48
User entered 'None (1)'	System	04 Sep 2020 00:36:48

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:19', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '77fbaab9-4d9a-4277-ba5b-a27689247a07'	System	04 Sep 2020 00:36:48
User entered 'No (N)'	System	04 Sep 2020 00:36:48

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '77fbaab9-4d9a-4277-ba5b-a27689247a07'	System	04 Sep 2020 00:36:48
User entered 'No (N)'	System	04 Sep 2020 00:36:48

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:38', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '77fbaab9-4d9a-4277-ba5b-a27689247a07'	System	04 Sep 2020 00:36:48
User entered 'None (1)'	System	04 Sep 2020 00:36:48

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '77fbaab9-4d9a-4277-ba5b-a27689247a07' User entered '03 Sep 2020 20:36'	System	04 Sep 2020 00:36:48
	System	04 Sep 2020 00:36:48

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 4'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:19', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'aa29b071-e242-4f1b-8f7d-eb8af0b23e88'	System	04 Sep 2020 23:22:47
User entered 'None (1)'	System	04 Sep 2020 23:22:47

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:22', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'aa29b071-e242-4f1b-8f7d-eb8af0b23e88'	System	04 Sep 2020 23:22:47
User entered 'No (N)'	System	04 Sep 2020 23:22:47

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'aa29b071-e242-4f1b-8f7d-eb8af0b23e88'	System	04 Sep 2020 23:22:47
User entered 'No (N)'	System	04 Sep 2020 23:22:47

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:40', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'aa29b071-e242-4f1b-8f7d-eb8af0b23e88'	System	04 Sep 2020 23:22:47
User entered 'None (1)'	System	04 Sep 2020 23:22:47

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:45', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'aa29b071-e242-4f1b-8f7d-eb8af0b23e88'	System	04 Sep 2020 23:22:47
User entered '04 Sep 2020 19:22'	System	04 Sep 2020 23:22:47

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 5'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:45', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'e0c9d8ff-2a54-406a-b71f-9482bf0bba25'	System	05 Sep 2020 22:26:02
User entered 'None (1)'	System	05 Sep 2020 22:26:02

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:48', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'e0c9d8ff-2a54-406a-b71f-9482bf0bba25'	System	05 Sep 2020 22:26:02
User entered 'No (N)'	System	05 Sep 2020 22:26:02

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'e0c9d8ff-2a54-406a-b71f-9482bf0bba25' User entered 'No (N)'	System	05 Sep 2020 22:26:02
	System	05 Sep 2020 22:26:02

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'e0c9d8ff-2a54-406a-b71f-9482bf0bba25'	System	05 Sep 2020 22:26:02
User entered 'None (1)'	System	05 Sep 2020 22:26:02

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:25:58', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'e0c9d8ff-2a54-406a-b71f-9482bf0bba25' User entered '05 Sep 2020 18:25'	System	05 Sep 2020 22:26:02
	System	05 Sep 2020 22:26:02

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 6'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:58:26', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '0dc1998d-2352-45c9-b45a-6f7eaa5d9118'	System	06 Sep 2020 22:58:44
User entered 'None (1)'	System	06 Sep 2020 22:58:44

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:58:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '0dc1998d-2352-45c9-b45a-6f7eaa5d9118' User entered 'No (N)'	System	06 Sep 2020 22:58:44
	System	06 Sep 2020 22:58:44

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:58:34', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '0dc1998d-2352-45c9-b45a-6f7eaa5d9118' User entered 'No (N)'	System	06 Sep 2020 22:58:44
	System	06 Sep 2020 22:58:44

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:58:38', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '0dc1998d-2352-45c9-b45a-6f7eaa5d9118' User entered 'None (1)'	System	06 Sep 2020 22:58:44
	System	06 Sep 2020 22:58:44

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:58:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '0dc1998d-2352-45c9-b45a-6f7eaa5d9118' User entered '06 Sep 2020 18:58'	System	06 Sep 2020 22:58:44
	System	06 Sep 2020 22:58:44

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 7'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:09', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8ab7e956-3149-430b-a067-766da19b3c38'	System	08 Sep 2020 00:28:26
User entered 'None (1)'	System	08 Sep 2020 00:28:26

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:13', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8ab7e956-3149-430b-a067-766da19b3c38'	System	08 Sep 2020 00:28:26
User entered 'No (N)'	System	08 Sep 2020 00:28:26

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:16', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8ab7e956-3149-430b-a067-766da19b3c38'	System	08 Sep 2020 00:28:26
User entered 'No (N)'	System	08 Sep 2020 00:28:26

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:20', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8ab7e956-3149-430b-a067-766da19b3c38'	System	08 Sep 2020 00:28:26
User entered 'None (1)'	System	08 Sep 2020 00:28:26

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8ab7e956-3149-430b-a067-766da19b3c38'	System	08 Sep 2020 00:28:26
User entered '07 Sep 2020 20:28'	System	08 Sep 2020 00:28:26

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:22', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71dd4f1c-ff22-4eb1-8880-a6bc2eaac3b3' User entered 'None (0)'	System	01 Sep 2020 14:59:48
	System	01 Sep 2020 14:59:48

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71dd4f1c-ff22-4eb1-8880-a6bc2eaac3b3' User entered 'None (0)'	System	01 Sep 2020 14:59:48
	System	01 Sep 2020 14:59:48

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:27', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71dd4f1c-ff22-4eb1-8880-a6bc2eaac3b3' User entered 'None (0)'	System	01 Sep 2020 14:59:48
	System	01 Sep 2020 14:59:48

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71dd4f1c-ff22-4eb1-8880-a6bc2eaac3b3' User entered 'None (0)'	System	01 Sep 2020 14:59:48
	System	01 Sep 2020 14:59:48

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71dd4f1c-ff22-4eb1-8880-a6bc2eaac3b3' User entered 'None (0)'	System	01 Sep 2020 14:59:48
	System	01 Sep 2020 14:59:48

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:35', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71dd4f1c-ff22-4eb1-8880-a6bc2eaac3b3' User entered 'None (0)'	System	01 Sep 2020 14:59:48
	System	01 Sep 2020 14:59:48

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71dd4f1c-ff22-4eb1-8880-a6bc2eaac3b3' User entered 'No (N)'	System	01 Sep 2020 14:59:48
	System	01 Sep 2020 14:59:48

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T10:59:45', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71dd4f1c-ff22-4eb1-8880-a6bc2eaac3b3'	System	01 Sep 2020 14:59:48
User entered '01 Sep 2020 10:59'	System	01 Sep 2020 14:59:48

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 10:44'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 13:14'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:10', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '69991e28-a61b-4b88-9225-097d6eadddf9' User entered 'None (0)'	System	01 Sep 2020 23:08:47
	System	01 Sep 2020 23:08:47

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:13', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '69991e28-a61b-4b88-9225-097d6eadddf9' User entered 'None (0)'	System	01 Sep 2020 23:08:47
	System	01 Sep 2020 23:08:47

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:17', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '69991e28-a61b-4b88-9225-097d6eaddf9' User entered 'None (0)'	System	01 Sep 2020 23:08:47
	System	01 Sep 2020 23:08:47

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '69991e28-a61b-4b88-9225-097d6eadddf9' User entered 'None (0)'	System	01 Sep 2020 23:08:47
	System	01 Sep 2020 23:08:47

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:26', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '69991e28-a61b-4b88-9225-097d6eadddf9' User entered 'None (0)'	System	01 Sep 2020 23:08:47
	System	01 Sep 2020 23:08:47

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '69991e28-a61b-4b88-9225-097d6eadddf9' User entered 'None (0)'	System	01 Sep 2020 23:08:47
	System	01 Sep 2020 23:08:47

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:36', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '69991e28-a61b-4b88-9225-097d6eadddf9' User entered 'No (N)'	System	01 Sep 2020 23:08:47
	System	01 Sep 2020 23:08:47

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-01T19:08:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '69991e28-a61b-4b88-9225-097d6eadddf9' User entered '01 Sep 2020 19:08'	System	01 Sep 2020 23:08:47
	System	01 Sep 2020 23:08:47

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Sep 2020 14:09'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 2'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:44:02', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '247ab478-b28a-4cab-96be-a9353c977fdd' User entered 'None (0)'	System	02 Sep 2020 22:44:44
	System	02 Sep 2020 22:44:44

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:44:13', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '247ab478-b28a-4cab-96be-a9353c977fdd' User entered 'None (0)'	System	02 Sep 2020 22:44:44
	System	02 Sep 2020 22:44:44

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:44:18', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '247ab478-b28a-4cab-96be-a9353c977fdd' User entered 'None (0)'	System	02 Sep 2020 22:44:44
	System	02 Sep 2020 22:44:44

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:44:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '247ab478-b28a-4cab-96be-a9353c977fdd' User entered 'None (0)'	System	02 Sep 2020 22:44:44
	System	02 Sep 2020 22:44:44

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:44:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '247ab478-b28a-4cab-96be-a9353c977fdd' User entered 'None (0)'	System	02 Sep 2020 22:44:44
	System	02 Sep 2020 22:44:44

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:44:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '247ab478-b28a-4cab-96be-a9353c977fdd' User entered 'None (0)'	System	02 Sep 2020 22:44:44
	System	02 Sep 2020 22:44:44

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:44:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '247ab478-b28a-4cab-96be-a9353c977fdd' User entered 'No (N)'	System	02 Sep 2020 22:44:44
	System	02 Sep 2020 22:44:44

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-02T18:44:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '247ab478-b28a-4cab-96be-a9353c977fdd' User entered '02 Sep 2020 18:44'	System	02 Sep 2020 22:44:44
	System	02 Sep 2020 22:44:44

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 3'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:49', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9c743d8b-d6b0-439c-8af8-87ff385c8450' User entered 'None (0)'	System	04 Sep 2020 00:37:19
	System	04 Sep 2020 00:37:19

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:36:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9c743d8b-d6b0-439c-8af8-87ff385c8450' User entered 'None (0)'	System	04 Sep 2020 00:37:19
	System	04 Sep 2020 00:37:19

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:37:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9c743d8b-d6b0-439c-8af8-87ff385c8450' User entered 'None (0)'	System	04 Sep 2020 00:37:19
	System	04 Sep 2020 00:37:19

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:37:04', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9c743d8b-d6b0-439c-8af8-87ff385c8450' User entered 'None (0)'	System	04 Sep 2020 00:37:19
	System	04 Sep 2020 00:37:19

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:37:07', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9c743d8b-d6b0-439c-8af8-87ff385c8450' User entered 'None (0)'	System	04 Sep 2020 00:37:19
	System	04 Sep 2020 00:37:19

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:37:10', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9c743d8b-d6b0-439c-8af8-87ff385c8450' User entered 'None (0)'	System	04 Sep 2020 00:37:19
	System	04 Sep 2020 00:37:19

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:37:13', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9c743d8b-d6b0-439c-8af8-87ff385c8450' User entered 'No (N)'	System	04 Sep 2020 00:37:19
	System	04 Sep 2020 00:37:19

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-03T20:37:18', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '9c743d8b-d6b0-439c-8af8-87ff385c8450' User entered '03 Sep 2020 20:37'	System	04 Sep 2020 00:37:19
	System	04 Sep 2020 00:37:19

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 4'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:51', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '977cb196-0c62-4d04-9ee5-499891c90d48' User entered 'None (0)'	System	04 Sep 2020 23:23:24
	System	04 Sep 2020 23:23:24

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:56', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '977cb196-0c62-4d04-9ee5-499891c90d48' User entered 'None (0)'	System	04 Sep 2020 23:23:24
	System	04 Sep 2020 23:23:24

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:22:59', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '977cb196-0c62-4d04-9ee5-499891c90d48' User entered 'None (0)'	System	04 Sep 2020 23:23:24
	System	04 Sep 2020 23:23:24

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:23:03', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '977cb196-0c62-4d04-9ee5-499891c90d48' User entered 'None (0)'	System	04 Sep 2020 23:23:24
	System	04 Sep 2020 23:23:24

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:23:06', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '977cb196-0c62-4d04-9ee5-499891c90d48' User entered 'None (0)'	System	04 Sep 2020 23:23:24
	System	04 Sep 2020 23:23:24

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:23:09', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '977cb196-0c62-4d04-9ee5-499891c90d48' User entered 'None (0)'	System	04 Sep 2020 23:23:24
	System	04 Sep 2020 23:23:24

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:23:16', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '977cb196-0c62-4d04-9ee5-499891c90d48' User entered 'No (N)'	System	04 Sep 2020 23:23:24
	System	04 Sep 2020 23:23:24

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-04T19:23:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '977cb196-0c62-4d04-9ee5-499891c90d48' User entered '04 Sep 2020 19:23'	System	04 Sep 2020 23:23:24
	System	04 Sep 2020 23:23:24

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 5'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:26:04', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c5ee8c7c-bca2-4935-b6b5-396b70b1c115' User entered 'None (0)'	System	05 Sep 2020 22:26:34
	System	05 Sep 2020 22:26:34

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:26:08', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c5ee8c7c-bca2-4935-b6b5-396b70b1c115' User entered 'None (0)'	System	05 Sep 2020 22:26:34
	System	05 Sep 2020 22:26:34

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:26:11', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c5ee8c7c-bca2-4935-b6b5-396b70b1c115' User entered 'None (0)'	System	05 Sep 2020 22:26:34
	System	05 Sep 2020 22:26:34

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:26:14', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c5ee8c7c-bca2-4935-b6b5-396b70b1c115' User entered 'None (0)'	System	05 Sep 2020 22:26:34
	System	05 Sep 2020 22:26:34

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:26:17', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c5ee8c7c-bca2-4935-b6b5-396b70b1c115' User entered 'None (0)'	System	05 Sep 2020 22:26:34
	System	05 Sep 2020 22:26:34

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:26:20', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c5ee8c7c-bca2-4935-b6b5-396b70b1c115' User entered 'None (0)'	System	05 Sep 2020 22:26:34
	System	05 Sep 2020 22:26:34

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:26:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c5ee8c7c-bca2-4935-b6b5-396b70b1c115'	System	05 Sep 2020 22:26:34
User entered 'No (N)'	System	05 Sep 2020 22:26:34

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-05T18:26:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c5ee8c7c-bca2-4935-b6b5-396b70b1c115'	System	05 Sep 2020 22:26:34
User entered '05 Sep 2020 18:26'	System	05 Sep 2020 22:26:34

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 6'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:59:02', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '48a06b3b-d18e-485b-a24e-0c3283909221' User entered 'None (0)'	System	06 Sep 2020 22:59:33
	System	06 Sep 2020 22:59:33

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:59:08', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '48a06b3b-d18e-485b-a24e-0c3283909221' User entered 'None (0)'	System	06 Sep 2020 22:59:33
	System	06 Sep 2020 22:59:33

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:59:11', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '48a06b3b-d18e-485b-a24e-0c3283909221' User entered 'None (0)'	System	06 Sep 2020 22:59:33
	System	06 Sep 2020 22:59:33

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:59:14', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '48a06b3b-d18e-485b-a24e-0c3283909221' User entered 'None (0)'	System	06 Sep 2020 22:59:33
	System	06 Sep 2020 22:59:33

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:59:17', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '48a06b3b-d18e-485b-a24e-0c3283909221' User entered 'None (0)'	System	06 Sep 2020 22:59:33
	System	06 Sep 2020 22:59:33

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:59:20', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '48a06b3b-d18e-485b-a24e-0c3283909221' User entered 'None (0)'	System	06 Sep 2020 22:59:33
	System	06 Sep 2020 22:59:33

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:59:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '48a06b3b-d18e-485b-a24e-0c3283909221' User entered 'No (N)'	System	06 Sep 2020 22:59:33
	System	06 Sep 2020 22:59:33

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-06T18:59:31', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '48a06b3b-d18e-485b-a24e-0c3283909221' User entered '06 Sep 2020 18:59'	System	06 Sep 2020 22:59:33
	System	06 Sep 2020 22:59:33

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 7'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:28', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8e18b40f-75e8-40b8-b9df-74e5d6b40036' User entered 'None (0)'	System	08 Sep 2020 00:29:12
	System	08 Sep 2020 00:29:12

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:38', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8e18b40f-75e8-40b8-b9df-74e5d6b40036' User entered 'None (0)'	System	08 Sep 2020 00:29:12
	System	08 Sep 2020 00:29:12

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8e18b40f-75e8-40b8-b9df-74e5d6b40036' User entered 'None (0)'	System	08 Sep 2020 00:29:12
	System	08 Sep 2020 00:29:12

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:48', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8e18b40f-75e8-40b8-b9df-74e5d6b40036' User entered 'None (0)'	System	08 Sep 2020 00:29:12
	System	08 Sep 2020 00:29:12

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:51', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8e18b40f-75e8-40b8-b9df-74e5d6b40036' User entered 'None (0)'	System	08 Sep 2020 00:29:12
	System	08 Sep 2020 00:29:12

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:28:54', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8e18b40f-75e8-40b8-b9df-74e5d6b40036' User entered 'None (0)'	System	08 Sep 2020 00:29:12
	System	08 Sep 2020 00:29:12

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:29:07', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8e18b40f-75e8-40b8-b9df-74e5d6b40036' User entered 'No (N)'	System	08 Sep 2020 00:29:12
	System	08 Sep 2020 00:29:12

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-07T20:29:10', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8e18b40f-75e8-40b8-b9df-74e5d6b40036' User entered '07 Sep 2020 20:29'	System	08 Sep 2020 00:29:12
	System	08 Sep 2020 00:29:12

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:33:09

US3662033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 15:10:37

US3662033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '08 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 15:10:37

US3662033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	09 Oct 2020 15:10:37

US3662033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:10:37

US3662033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:27:35

US3662033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	29 Sep 2020 13:27:35

US3662033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 16:10:17

US3662033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '15 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 16:10:17

US3662033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	09 Oct 2020 16:10:17

US3662033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 16:10:17

US3662033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:27:43

US3662033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	29 Sep 2020 13:27:43

US3662033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:15:02

US3662033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '24 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:15:02

US3662033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	09 Oct 2020 17:15:02

US3662033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:15:02

US3662033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:27:50

US3662033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	29 Sep 2020 13:27:50

US3662033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:22:01

US3662033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '29 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:22:01

US3662033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	09 Oct 2020 17:22:01

US3662033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'VISIT2'	System	09 Oct 2020 17:22:01

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '29 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '08:20'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '29 Sep 2020 08:20'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '97.9' F	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Other (Other)'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '60'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'bpm'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '16'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'breaths/min'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '153'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '73'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '29 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '09:55'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '29 Sep 2020 09:55'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '97.8' F	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Other (Other)'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '60'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'bpm'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '12'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'breaths/min'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '153'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '78'	Brenda Miller (b) (4)	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	09 Oct 2020 17:23:49

US3662033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:24:01

US3662033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '29 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:24:01

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

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)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '29 Sep 2020'	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '09:24'	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '29 Sep 2020 09:24'	System	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) michelle saemann (b) (4)	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'ONCE'	System	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 13:28:45

US3662033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:24:46

US3662033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '29 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:24:46

US3662033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '08:45'	Brenda Miller (b) (4)	09 Oct 2020 17:24:46

US3662033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '29 Sep 2020 08:45'	System	09 Oct 2020 17:24:46

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '29 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '08:40'	Brenda Miller (b) (4)	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '29 Sep 2020 08:40'	System	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered empty.	System	09 Oct 2020 17:25:07

US3662033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:25:15

US3662033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	09 Oct 2020 17:25:15

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:56:29', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad296daf-1a97-4be8-a36a-71b3033c33be' User entered 'Yes (Y)'	System	29 Sep 2020 13:56:52
	System	29 Sep 2020 13:56:52

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:56:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad296daf-1a97-4be8-a36a-71b3033c33be' User entered '97.8'	System	29 Sep 2020 13:56:52
	System	29 Sep 2020 13:56:52

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:56:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad296daf-1a97-4be8-a36a-71b3033c33be' User entered 'No (N)'	System	29 Sep 2020 13:56:52
	System	29 Sep 2020 13:56:52

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:56:50', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad296daf-1a97-4be8-a36a-71b3033c33be' User entered '29 Sep 2020 09:56'	System	29 Sep 2020 13:56:52
	System	29 Sep 2020 13:56:52

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '29 Sep 2020 09:44'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '29 Sep 2020 12:14'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:03:17', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '111dfcb8-3ae5-46a2-a7a9-7004a2286152' User entered 'Yes (Y)'	System	29 Sep 2020 23:03:59
	System	29 Sep 2020 23:03:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:03:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '111dfcb8-3ae5-46a2-a7a9-7004a2286152' User entered '97.9'	System	29 Sep 2020 23:03:59
	System	29 Sep 2020 23:03:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:03:31', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '111dfcb8-3ae5-46a2-a7a9-7004a2286152'	System	29 Sep 2020 23:03:59
User entered 'Yes (Y)'	System	29 Sep 2020 23:03:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant contacted and medication recorded on med page' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:23:23
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:03:47', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '111dfcb8-3ae5-46a2-a7a9-7004a2286152' User entered '1'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:58:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	29 Sep 2020 23:03:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:03:47', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '111dfcb8-3ae5-46a2-a7a9-7004a2286152' User entered '1'	System	29 Sep 2020 23:03:59
User entered '1'	System	29 Sep 2020 23:03:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:03:47', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '111dfcb8-3ae5-46a2-a7a9-7004a2286152' User entered '0'	System	29 Sep 2020 23:03:59
	System	29 Sep 2020 23:03:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:03:57', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '111dfcb8-3ae5-46a2-a7a9-7004a2286152' User entered '29 Sep 2020 19:03'	System	29 Sep 2020 23:03:59
	System	29 Sep 2020 23:03:59

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '29 Sep 2020 13:09'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 2'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:23:50', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b1cc30f-78d0-4bde-9aa2-ee83ca59117d' User entered 'Yes (Y)'	System	30 Sep 2020 22:24:48
	System	30 Sep 2020 22:24:48

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:23:56', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b1cc30f-78d0-4bde-9aa2-ee83ca59117d' User entered '98.0'	System	30 Sep 2020 22:24:48
	System	30 Sep 2020 22:24:48

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:24:20', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b1cc30f-78d0-4bde-9aa2-ee83ca59117d'	System	30 Sep 2020 22:24:48
User entered 'Yes (Y)'	System	30 Sep 2020 22:24:48

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant contacted and medication recorded on med page' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:23:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:24:37', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b1cc30f-78d0-4bde-9aa2-ee83ca59117d' User entered '1'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:59:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Sep 2020 22:24:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:24:37', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b1cc30f-78d0-4bde-9aa2-ee83ca59117d' User entered '1'	System	30 Sep 2020 22:24:48
User entered '1'	System	30 Sep 2020 22:24:48

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:24:37', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b1cc30f-78d0-4bde-9aa2-ee83ca59117d' User entered '0'	System	30 Sep 2020 22:24:48
	System	30 Sep 2020 22:24:48

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:24:46', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b1cc30f-78d0-4bde-9aa2-ee83ca59117d' User entered '30 Sep 2020 18:24'	System	30 Sep 2020 22:24:48
	System	30 Sep 2020 22:24:48

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 3'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bce99be7-564a-486d-9ce2-c07cb6aba434' User entered 'Yes (Y)'	System	01 Oct 2020 22:23:24
	System	01 Oct 2020 22:23:24

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:06', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bce99be7-564a-486d-9ce2-c07cb6aba434' User entered '99.3'	System	01 Oct 2020 22:23:24
	System	01 Oct 2020 22:23:24

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:12', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bce99be7-564a-486d-9ce2-c07cb6aba434'	System	01 Oct 2020 22:23:24
User entered 'No (N)'	System	01 Oct 2020 22:23:24

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:17', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bce99be7-564a-486d-9ce2-c07cb6aba434' User entered '01 Oct 2020 18:23'	System	01 Oct 2020 22:23:24
	System	01 Oct 2020 22:23:24

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 4'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:18', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b9cd306-afda-48eb-ad58-cebc9c6c79e1' User entered 'Yes (Y)'	System	02 Oct 2020 23:29:37
	System	02 Oct 2020 23:29:37

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b9cd306-afda-48eb-ad58-cebc9c6c79e1' User entered '98.0'	System	02 Oct 2020 23:29:37
	System	02 Oct 2020 23:29:37

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:28', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b9cd306-afda-48eb-ad58-cebc9c6c79e1' User entered 'No (N)'	System	02 Oct 2020 23:29:37
	System	02 Oct 2020 23:29:37

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7b9cd306-afda-48eb-ad58-cebc9c6c79e1' User entered '02 Oct 2020 19:29'	System	02 Oct 2020 23:29:37
	System	02 Oct 2020 23:29:37

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 5'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:09:19', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '15aba018-a7d5-4c57-a74c-6236d291faf3' User entered 'Yes (Y)'	System	03 Oct 2020 23:09:54
	System	03 Oct 2020 23:09:54

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:09:27', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '15aba018-a7d5-4c57-a74c-6236d291faf3' User entered '99.3'	System	03 Oct 2020 23:09:54
	System	03 Oct 2020 23:09:54

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:09:35', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '15aba018-a7d5-4c57-a74c-6236d291faf3' User entered 'Yes (Y)'	System	03 Oct 2020 23:09:54
	System	03 Oct 2020 23:09:54

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant contacted and medication recorded on med page' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:24:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Brenda Miller (b) (4)	13 Oct 2020 14:00:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:09:42', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '15aba018-a7d5-4c57-a74c-6236d291faf3'	(b) (4)	
User entered '1'	System	03 Oct 2020 23:09:54
	System	03 Oct 2020 23:09:54
	System	03 Oct 2020 23:09:54

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:09:42', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '15aba018-a7d5-4c57-a74c-6236d291faf3' User entered '0'	System	03 Oct 2020 23:09:54
	System	03 Oct 2020 23:09:54

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:09:51', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '15aba018-a7d5-4c57-a74c-6236d291faf3' User entered '03 Oct 2020 19:09'	System	03 Oct 2020 23:09:54
	System	03 Oct 2020 23:09:54

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 6'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:57:48', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a409c1c0-7707-4494-91e4-ddd652b6e12c' User entered 'Yes (Y)'	System	05 Oct 2020 12:58:08
	System	05 Oct 2020 12:58:08

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:57:54', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a409c1c0-7707-4494-91e4-ddd652b6e12c' User entered '97.9'	System	05 Oct 2020 12:58:08
	System	05 Oct 2020 12:58:08

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:57:59', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a409c1c0-7707-4494-91e4-ddd652b6e12c' User entered 'No (N)'	System	05 Oct 2020 12:58:08
	System	05 Oct 2020 12:58:08

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:03', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'a409c1c0-7707-4494-91e4-ddd652b6e12c' User entered '05 Oct 2020 08:58'	System	05 Oct 2020 12:58:08
	System	05 Oct 2020 12:58:08

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 7'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T18:59:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6d4feaf8-207a-4f36-8c29-b59ba5b35481' User entered 'Yes (Y)'	System	05 Oct 2020 22:59:47
	System	05 Oct 2020 22:59:47

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T18:59:36', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6d4feaf8-207a-4f36-8c29-b59ba5b35481' User entered '97.5'	System	05 Oct 2020 22:59:47
	System	05 Oct 2020 22:59:47

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T18:59:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6d4feaf8-207a-4f36-8c29-b59ba5b35481' User entered 'No (N)'	System	05 Oct 2020 22:59:47
	System	05 Oct 2020 22:59:47

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T18:59:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6d4feaf8-207a-4f36-8c29-b59ba5b35481' User entered '05 Oct 2020 18:59'	System	05 Oct 2020 22:59:47
	System	05 Oct 2020 22:59:47

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:09', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '13418b26-40d0-43b3-a629-3262e4060f88'	System	29 Sep 2020 13:57:40
User entered 'None (1)'	System	29 Sep 2020 13:57:40

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:25', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '13418b26-40d0-43b3-a629-3262e4060f88'	System	29 Sep 2020 13:57:40
User entered 'No (N)'	System	29 Sep 2020 13:57:40

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '13418b26-40d0-43b3-a629-3262e4060f88'	System	29 Sep 2020 13:57:40
User entered 'No (N)'	System	29 Sep 2020 13:57:40

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:35', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '13418b26-40d0-43b3-a629-3262e4060f88'	System	29 Sep 2020 13:57:40
User entered 'None (1)'	System	29 Sep 2020 13:57:40

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:38', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '13418b26-40d0-43b3-a629-3262e4060f88'	System	29 Sep 2020 13:57:40
User entered '29 Sep 2020 09:57'	System	29 Sep 2020 13:57:40

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '29 Sep 2020 09:44'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '29 Sep 2020 12:14'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:04:12', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd52b0cea-a75f-4c92-8943-0d2ae7b70f55'	System	29 Sep 2020 23:04:38
User entered 'None (1)'	System	29 Sep 2020 23:04:38

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:04:16', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd52b0cea-a75f-4c92-8943-0d2ae7b70f55'	System	29 Sep 2020 23:04:38
User entered 'No (N)'	System	29 Sep 2020 23:04:38

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:04:20', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd52b0cea-a75f-4c92-8943-0d2ae7b70f55' User entered 'No (N)'	System	29 Sep 2020 23:04:38
	System	29 Sep 2020 23:04:38

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:04:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd52b0cea-a75f-4c92-8943-0d2ae7b70f55'	System	29 Sep 2020 23:04:38
User entered 'None (1)'	System	29 Sep 2020 23:04:38

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:04:31', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd52b0cea-a75f-4c92-8943-0d2ae7b70f55' User entered '29 Sep 2020 19:04'	System	29 Sep 2020 23:04:38
	System	29 Sep 2020 23:04:38

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '29 Sep 2020 13:09'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 2'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:24:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '86c3169c-ec5f-49d3-9de9-b05984743b5d' User entered 'None (1)'	System	30 Sep 2020 22:25:16
	System	30 Sep 2020 22:25:16

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:24:59', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '86c3169c-ec5f-49d3-9de9-b05984743b5d' User entered 'No (N)'	System	30 Sep 2020 22:25:16
	System	30 Sep 2020 22:25:16

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:03', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '86c3169c-ec5f-49d3-9de9-b05984743b5d' User entered 'No (N)'	System	30 Sep 2020 22:25:16
	System	30 Sep 2020 22:25:16

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:10', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '86c3169c-ec5f-49d3-9de9-b05984743b5d' User entered 'None (1)'	System	30 Sep 2020 22:25:16
	System	30 Sep 2020 22:25:16

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:14', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '86c3169c-ec5f-49d3-9de9-b05984743b5d' User entered '30 Sep 2020 18:25'	System	30 Sep 2020 22:25:16
	System	30 Sep 2020 22:25:16

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 3'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:26', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '10b18bce-ab54-4a40-a4bc-22d82dab2a24'	System	01 Oct 2020 22:23:57
User entered 'None (1)'	System	01 Oct 2020 22:23:57

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:37', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '10b18bce-ab54-4a40-a4bc-22d82dab2a24' User entered 'No (N)'	System	01 Oct 2020 22:23:57
	System	01 Oct 2020 22:23:57

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:42', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '10b18bce-ab54-4a40-a4bc-22d82dab2a24' User entered 'No (N)'	System	01 Oct 2020 22:23:57
	System	01 Oct 2020 22:23:57

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:49', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '10b18bce-ab54-4a40-a4bc-22d82dab2a24'	System	01 Oct 2020 22:23:57
User entered 'None (1)'	System	01 Oct 2020 22:23:57

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '10b18bce-ab54-4a40-a4bc-22d82dab2a24' User entered '01 Oct 2020 18:23'	System	01 Oct 2020 22:23:57
	System	01 Oct 2020 22:23:57

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 4'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '72dccef0-7574-45eb-a34c-e683f636750c'	System	02 Oct 2020 23:29:56
User entered 'None (1)'	System	02 Oct 2020 23:29:56

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:42', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '72dccef0-7574-45eb-a34c-e683f636750c'	System	02 Oct 2020 23:29:56
User entered 'No (N)'	System	02 Oct 2020 23:29:56

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:46', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '72dccef0-7574-45eb-a34c-e683f636750c'	System	02 Oct 2020 23:29:56
User entered 'No (N)'	System	02 Oct 2020 23:29:56

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:51', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '72dccef0-7574-45eb-a34c-e683f636750c'	System	02 Oct 2020 23:29:56
User entered 'None (1)'	System	02 Oct 2020 23:29:56

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:29:54', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '72dccef0-7574-45eb-a34c-e683f636750c' User entered '02 Oct 2020 19:29'	System	02 Oct 2020 23:29:56
	System	02 Oct 2020 23:29:56

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 5'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:09:57', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '301b652f-d2b4-4d4f-94c2-d7806442201b' User entered 'None (1)'	System	03 Oct 2020 23:10:12
	System	03 Oct 2020 23:10:12

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '301b652f-d2b4-4d4f-94c2-d7806442201b' User entered 'No (N)'	System	03 Oct 2020 23:10:12
	System	03 Oct 2020 23:10:12

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:04', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '301b652f-d2b4-4d4f-94c2-d7806442201b' User entered 'No (N)'	System	03 Oct 2020 23:10:12
	System	03 Oct 2020 23:10:12

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:07', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '301b652f-d2b4-4d4f-94c2-d7806442201b' User entered 'None (1)'	System	03 Oct 2020 23:10:12
	System	03 Oct 2020 23:10:12

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:10', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '301b652f-d2b4-4d4f-94c2-d7806442201b' User entered '03 Oct 2020 19:10'	System	03 Oct 2020 23:10:12
	System	03 Oct 2020 23:10:12

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 6'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:08', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'abdaf689-d4f3-4d2f-aa94-513ecc0aa33f' User entered 'None (1)'	System	05 Oct 2020 12:58:28
	System	05 Oct 2020 12:58:28

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:13', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'abdaf689-d4f3-4d2f-aa94-513ecc0aa33f' User entered 'No (N)'	System	05 Oct 2020 12:58:28
	System	05 Oct 2020 12:58:28

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:16', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'abdaf689-d4f3-4d2f-aa94-513ecc0aa33f' User entered 'No (N)'	System	05 Oct 2020 12:58:28
	System	05 Oct 2020 12:58:28

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:20', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'abdaf689-d4f3-4d2f-aa94-513ecc0aa33f' User entered 'None (1)'	System	05 Oct 2020 12:58:28
	System	05 Oct 2020 12:58:28

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'abdaf689-d4f3-4d2f-aa94-513ecc0aa33f' User entered '05 Oct 2020 08:58'	System	05 Oct 2020 12:58:28
	System	05 Oct 2020 12:58:28

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 7'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T18:59:50', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'cc0c3431-da68-4014-843b-de503c2d48af'	System	05 Oct 2020 23:00:21
User entered 'None (1)'	System	05 Oct 2020 23:00:21

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T18:59:53', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'cc0c3431-da68-4014-843b-de503c2d48af' User entered 'No (N)'	System	05 Oct 2020 23:00:21
	System	05 Oct 2020 23:00:21

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T18:59:56', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'cc0c3431-da68-4014-843b-de503c2d48af' User entered 'No (N)'	System	05 Oct 2020 23:00:21
	System	05 Oct 2020 23:00:21

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:08', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'cc0c3431-da68-4014-843b-de503c2d48af' User entered 'None (1)'	System	05 Oct 2020 23:00:21
	System	05 Oct 2020 23:00:21

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:18', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'cc0c3431-da68-4014-843b-de503c2d48af' User entered '05 Oct 2020 19:00'	System	05 Oct 2020 23:00:21
	System	05 Oct 2020 23:00:21

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:44', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6bc9e1d9-64db-442c-bb5a-a442bc65ca7a' User entered 'None (0)'	System	29 Sep 2020 13:58:23
	System	29 Sep 2020 13:58:23

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6bc9e1d9-64db-442c-bb5a-a442bc65ca7a' User entered 'None (0)'	System	29 Sep 2020 13:58:23
	System	29 Sep 2020 13:58:23

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6bc9e1d9-64db-442c-bb5a-a442bc65ca7a' User entered 'None (0)'	System	29 Sep 2020 13:58:23
	System	29 Sep 2020 13:58:23

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:57:58', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6bc9e1d9-64db-442c-bb5a-a442bc65ca7a' User entered 'None (0)'	System	29 Sep 2020 13:58:23
	System	29 Sep 2020 13:58:23

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:58:01', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6bc9e1d9-64db-442c-bb5a-a442bc65ca7a' User entered 'None (0)'	System	29 Sep 2020 13:58:23
	System	29 Sep 2020 13:58:23

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:58:04', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6bc9e1d9-64db-442c-bb5a-a442bc65ca7a' User entered 'None (0)'	System	29 Sep 2020 13:58:23
	System	29 Sep 2020 13:58:23

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:58:09', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6bc9e1d9-64db-442c-bb5a-a442bc65ca7a' User entered 'No (N)'	System	29 Sep 2020 13:58:23
	System	29 Sep 2020 13:58:23

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T09:58:11', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '6bc9e1d9-64db-442c-bb5a-a442bc65ca7a' User entered '29 Sep 2020 09:58'	System	29 Sep 2020 13:58:23
	System	29 Sep 2020 13:58:23

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '29 Sep 2020 09:44'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '29 Sep 2020 12:14'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:04:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '687220dc-fbe5-4fa0-96f6-349df1e41539'	System	29 Sep 2020 23:05:58
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:05:58

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '687220dc-fbe5-4fa0-96f6-349df1e41539'	System	29 Sep 2020 23:05:58
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:05:58

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:05:04', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '687220dc-fbe5-4fa0-96f6-349df1e41539' User entered 'None (0)'	System	29 Sep 2020 23:05:58
	System	29 Sep 2020 23:05:58

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:05:29', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '687220dc-fbe5-4fa0-96f6-349df1e41539'	System	29 Sep 2020 23:05:58
User entered 'No interference with activity (1)'	System	29 Sep 2020 23:05:58

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:05:32', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '687220dc-fbe5-4fa0-96f6-349df1e41539' User entered 'None (0)'	System	29 Sep 2020 23:05:58
	System	29 Sep 2020 23:05:58

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:05:46', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '687220dc-fbe5-4fa0-96f6-349df1e41539' User entered 'None (0)'	System	29 Sep 2020 23:05:58
	System	29 Sep 2020 23:05:58

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:05:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '687220dc-fbe5-4fa0-96f6-349df1e41539' User entered 'No (N)'	System	29 Sep 2020 23:05:58
	System	29 Sep 2020 23:05:58

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-29T19:05:56', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '687220dc-fbe5-4fa0-96f6-349df1e41539' User entered '29 Sep 2020 19:05'	System	29 Sep 2020 23:05:58
	System	29 Sep 2020 23:05:58

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '29 Sep 2020 13:09'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 2'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:22', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c2db3f98-fc06-4d95-966e-8502a5393a55' User entered 'None (0)'	System	30 Sep 2020 22:26:01
	System	30 Sep 2020 22:26:01

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:29', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c2db3f98-fc06-4d95-966e-8502a5393a55' User entered 'None (0)'	System	30 Sep 2020 22:26:01
	System	30 Sep 2020 22:26:01

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c2db3f98-fc06-4d95-966e-8502a5393a55' User entered 'None (0)'	System	30 Sep 2020 22:26:01
	System	30 Sep 2020 22:26:01

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:38', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c2db3f98-fc06-4d95-966e-8502a5393a55' User entered 'None (0)'	System	30 Sep 2020 22:26:01
	System	30 Sep 2020 22:26:01

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:42', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c2db3f98-fc06-4d95-966e-8502a5393a55' User entered 'None (0)'	System	30 Sep 2020 22:26:01
	System	30 Sep 2020 22:26:01

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:45', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c2db3f98-fc06-4d95-966e-8502a5393a55' User entered 'None (0)'	System	30 Sep 2020 22:26:01
	System	30 Sep 2020 22:26:01

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c2db3f98-fc06-4d95-966e-8502a5393a55'	System	30 Sep 2020 22:26:01
User entered 'No (N)'	System	30 Sep 2020 22:26:01

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-09-30T18:25:58', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c2db3f98-fc06-4d95-966e-8502a5393a55'	System	30 Sep 2020 22:26:01
User entered '30 Sep 2020 18:25'	System	30 Sep 2020 22:26:01

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 3'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:23:59', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bc122cef-7a99-4e26-a893-3de9d45c6407' User entered 'None (0)'	System	01 Oct 2020 22:24:54
	System	01 Oct 2020 22:24:54

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:24:17', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bc122cef-7a99-4e26-a893-3de9d45c6407' User entered 'None (0)'	System	01 Oct 2020 22:24:54
	System	01 Oct 2020 22:24:54

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:24:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bc122cef-7a99-4e26-a893-3de9d45c6407'	System	01 Oct 2020 22:24:54
User entered 'No interference with activity (1)'	System	01 Oct 2020 22:24:54

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:24:36', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bc122cef-7a99-4e26-a893-3de9d45c6407' User entered 'None (0)'	System	01 Oct 2020 22:24:54
	System	01 Oct 2020 22:24:54

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:24:41', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bc122cef-7a99-4e26-a893-3de9d45c6407' User entered 'None (0)'	System	01 Oct 2020 22:24:54
	System	01 Oct 2020 22:24:54

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:24:44', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bc122cef-7a99-4e26-a893-3de9d45c6407' User entered 'None (0)'	System	01 Oct 2020 22:24:54
	System	01 Oct 2020 22:24:54

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:24:48', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bc122cef-7a99-4e26-a893-3de9d45c6407'	System	01 Oct 2020 22:24:54
User entered 'No (N)'	System	01 Oct 2020 22:24:54

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-01T18:24:51', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'bc122cef-7a99-4e26-a893-3de9d45c6407' User entered '01 Oct 2020 18:24'	System	01 Oct 2020 22:24:54
	System	01 Oct 2020 22:24:54

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 4'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:30:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ab484ecd-d9ce-4b30-93a1-d7de3732165a' User entered 'None (0)'	System	02 Oct 2020 23:30:29
	System	02 Oct 2020 23:30:29

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:30:03', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ab484ecd-d9ce-4b30-93a1-d7de3732165a' User entered 'None (0)'	System	02 Oct 2020 23:30:29
	System	02 Oct 2020 23:30:29

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:30:08', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ab484ecd-d9ce-4b30-93a1-d7de3732165a' User entered 'None (0)'	System	02 Oct 2020 23:30:29
	System	02 Oct 2020 23:30:29

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:30:13', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ab484ecd-d9ce-4b30-93a1-d7de3732165a' User entered 'None (0)'	System	02 Oct 2020 23:30:29
	System	02 Oct 2020 23:30:29

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:30:16', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ab484ecd-d9ce-4b30-93a1-d7de3732165a' User entered 'None (0)'	System	02 Oct 2020 23:30:29
	System	02 Oct 2020 23:30:29

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:30:19', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ab484ecd-d9ce-4b30-93a1-d7de3732165a' User entered 'None (0)'	System	02 Oct 2020 23:30:29
	System	02 Oct 2020 23:30:29

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:30:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ab484ecd-d9ce-4b30-93a1-d7de3732165a' User entered 'No (N)'	System	02 Oct 2020 23:30:29
	System	02 Oct 2020 23:30:29

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-02T19:30:27', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ab484ecd-d9ce-4b30-93a1-d7de3732165a' User entered '02 Oct 2020 19:30'	System	02 Oct 2020 23:30:29
	System	02 Oct 2020 23:30:29

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 5'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:17', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7890ba58-5f86-4e03-a941-c8b8b9f38d0b' User entered 'None (0)'	System	03 Oct 2020 23:10:47
	System	03 Oct 2020 23:10:47

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:20', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7890ba58-5f86-4e03-a941-c8b8b9f38d0b' User entered 'None (0)'	System	03 Oct 2020 23:10:47
	System	03 Oct 2020 23:10:47

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7890ba58-5f86-4e03-a941-c8b8b9f38d0b' User entered 'None (0)'	System	03 Oct 2020 23:10:47
	System	03 Oct 2020 23:10:47

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:27', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7890ba58-5f86-4e03-a941-c8b8b9f38d0b' User entered 'None (0)'	System	03 Oct 2020 23:10:47
	System	03 Oct 2020 23:10:47

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7890ba58-5f86-4e03-a941-c8b8b9f38d0b' User entered 'None (0)'	System	03 Oct 2020 23:10:47
	System	03 Oct 2020 23:10:47

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:34', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7890ba58-5f86-4e03-a941-c8b8b9f38d0b' User entered 'None (0)'	System	03 Oct 2020 23:10:47
	System	03 Oct 2020 23:10:47

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:37', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7890ba58-5f86-4e03-a941-c8b8b9f38d0b' User entered 'No (N)'	System	03 Oct 2020 23:10:47
	System	03 Oct 2020 23:10:47

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-03T19:10:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '7890ba58-5f86-4e03-a941-c8b8b9f38d0b' User entered '03 Oct 2020 19:10'	System	03 Oct 2020 23:10:47
	System	03 Oct 2020 23:10:47

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 6'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:29', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '87186dca-13c2-415a-80b0-501e0ae92482' User entered 'None (0)'	System	05 Oct 2020 12:58:52
	System	05 Oct 2020 12:58:52

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:32', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '87186dca-13c2-415a-80b0-501e0ae92482' User entered 'None (0)'	System	05 Oct 2020 12:58:52
	System	05 Oct 2020 12:58:52

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:35', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '87186dca-13c2-415a-80b0-501e0ae92482' User entered 'None (0)'	System	05 Oct 2020 12:58:52
	System	05 Oct 2020 12:58:52

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:38', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '87186dca-13c2-415a-80b0-501e0ae92482' User entered 'None (0)'	System	05 Oct 2020 12:58:52
	System	05 Oct 2020 12:58:52

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:41', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '87186dca-13c2-415a-80b0-501e0ae92482' User entered 'None (0)'	System	05 Oct 2020 12:58:52
	System	05 Oct 2020 12:58:52

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:44', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '87186dca-13c2-415a-80b0-501e0ae92482' User entered 'None (0)'	System	05 Oct 2020 12:58:52
	System	05 Oct 2020 12:58:52

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:47', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '87186dca-13c2-415a-80b0-501e0ae92482' User entered 'No (N)'	System	05 Oct 2020 12:58:52
	System	05 Oct 2020 12:58:52

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T08:58:50', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '87186dca-13c2-415a-80b0-501e0ae92482' User entered '05 Oct 2020 08:58'	System	05 Oct 2020 12:58:52
	System	05 Oct 2020 12:58:52

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
Data entry locked.	System	29 Sep 2020 13:28:45
User entered 'Day 7'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:23', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f9dfd15f-17df-43d5-be48-1ef5b9659c4b' User entered 'None (0)'	System	05 Oct 2020 23:00:50
	System	05 Oct 2020 23:00:50

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:26', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f9dfd15f-17df-43d5-be48-1ef5b9659c4b' User entered 'None (0)'	System	05 Oct 2020 23:00:50
	System	05 Oct 2020 23:00:50

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:29', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f9dfd15f-17df-43d5-be48-1ef5b9659c4b' User entered 'None (0)'	System	05 Oct 2020 23:00:50
	System	05 Oct 2020 23:00:50

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:34', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f9dfd15f-17df-43d5-be48-1ef5b9659c4b' User entered 'None (0)'	System	05 Oct 2020 23:00:50
	System	05 Oct 2020 23:00:50

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:36', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f9dfd15f-17df-43d5-be48-1ef5b9659c4b' User entered 'None (0)'	System	05 Oct 2020 23:00:50
	System	05 Oct 2020 23:00:50

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f9dfd15f-17df-43d5-be48-1ef5b9659c4b' User entered 'None (0)'	System	05 Oct 2020 23:00:50
	System	05 Oct 2020 23:00:50

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

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 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:45', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f9dfd15f-17df-43d5-be48-1ef5b9659c4b' User entered 'No (N)'	System	05 Oct 2020 23:00:50
	System	05 Oct 2020 23:00:50

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-10-05T19:00:49', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f9dfd15f-17df-43d5-be48-1ef5b9659c4b' User entered '05 Oct 2020 19:00'	System	05 Oct 2020 23:00:50
	System	05 Oct 2020 23:00:50

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:28:45

US3662033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:21:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:57
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:28:45

US3662033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:30:48

US3662033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '07 Oct 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:30:48

US3662033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	09 Oct 2020 17:30:48

US3662033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:30:48

US3662033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:30:54

US3662033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	09 Oct 2020 17:30:54

US3662033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Oct 2020 17:59:21

US3662033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 04:58:53
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:00:04
answered with 'Safety call day 43 completed one day out of window-Coordinator error' (Site from System).		
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Oct 2020 17:59:21
User entered '17 Oct 2020'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 17:59:21

US3662033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	23 Oct 2020 17:59:21

US3662033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	23 Oct 2020 17:59:21

US3662033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Oct 2020 18:00:11

US3662033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	23 Oct 2020 18:00:11

US3662033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	04 Nov 2020 14:19:07

US3662033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '20 Oct 2020'	Brenda Miller (b) (4)	04 Nov 2020 14:19:07

US3662033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	04 Nov 2020 14:19:07

US3662033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	04 Nov 2020 14:19:07

US3662033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 19:12:36

US3662033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	31 Oct 2020 19:12:36

US3662033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 19:12:53

US3662033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '28 Oct 2020'	Brenda Miller (b) (4)	31 Oct 2020 19:12:53

US3662033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	31 Oct 2020 19:12:53

US3662033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'VISIT3'	System	31 Oct 2020 19:12:53

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '28 Oct 2020'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '12:04'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '28 Oct 2020 12:04'	System	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '97.6' F	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Other (Other)'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '68'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'bpm'	System	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '16'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'breaths/min'	System	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '133'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '73'	Brenda Miller (b) (4)	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'mmHg'	System	31 Oct 2020 19:13:48

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46

US3662033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46

US3662033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 19:14:01

US3662033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '28 Oct 2020'	Brenda Miller (b) (4)	31 Oct 2020 19:14:01

US3662033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 19:14:32

US3662033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '28 Oct 2020'	Brenda Miller (b) (4)	31 Oct 2020 19:14:32

US3662033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered '12:05'	Brenda Miller (b) (4)	31 Oct 2020 19:14:32

US3662033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '28 Oct 2020 12:05'	System	31 Oct 2020 19:14:32

US3662033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:13
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 19:14:49

US3662033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered '1'	System	31 Oct 2020 19:14:49

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 64'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28
Data entry locked.	System	01 Sep 2020 14:33:09
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:32:28
Data entry locked.	System	01 Sep 2020 14:33:09
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 71'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-08T07:16:32', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '557d4ff5-af5b-4de2-b978-65ea3377ef87' User entered 'No (N)'	System	08 Nov 2020 12:17:18
	System	08 Nov 2020 12:17:18

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-08T07:16:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '557d4ff5-af5b-4de2-b978-65ea3377ef87'	System	08 Nov 2020 12:17:18
User entered 'Yes (Y)'	System	08 Nov 2020 12:17:18

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-08T07:16:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '557d4ff5-af5b-4de2-b978-65ea3377ef87'	System	08 Nov 2020 12:17:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Nov 2020 12:17:18

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-08T07:17:10', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '557d4ff5-af5b-4de2-b978-65ea3377ef87' User entered '08 Nov 2020 07:17:10'	System	08 Nov 2020 12:17:18
	System	08 Nov 2020 12:17:18

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	01 Sep 2020 14:33:09
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	01 Sep 2020 14:33:09
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	01 Sep 2020 14:33:09
User entered 'Day 78'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-15T08:21:43', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71717b8e-7be9-4832-9f9c-4c5e23ddab93'	System	15 Nov 2020 13:22:08
User entered 'No (N)'	System	15 Nov 2020 13:22:08

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-15T08:21:57', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71717b8e-7be9-4832-9f9c-4c5e23ddab93'	System	15 Nov 2020 13:22:08
User entered 'No (N)'	System	15 Nov 2020 13:22:08

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-15T08:22:05', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '71717b8e-7be9-4832-9f9c-4c5e23ddab93' User entered '15 Nov 2020 08:22:05'	System	15 Nov 2020 13:22:08
	System	15 Nov 2020 13:22:08

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	01 Sep 2020 14:33:09
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 14:33:09

US3662033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:38:02
Data entry locked.	System	01 Sep 2020 14:33:09
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 14:33:09

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-22T21:31:15', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3f6d9c89-34bc-4f35-818e-86cebf6ce56e'	System	23 Nov 2020 02:31:38
User entered 'No (N)'	System	23 Nov 2020 02:31:38

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-22T21:31:27', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3f6d9c89-34bc-4f35-818e-86cebf6ce56e'	System	23 Nov 2020 02:31:38
User entered 'No (N)'	System	23 Nov 2020 02:31:38

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-22T21:31:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3f6d9c89-34bc-4f35-818e-86cebf6ce56e' User entered '22 Nov 2020 21:31:33'	System	23 Nov 2020 02:31:38
	System	23 Nov 2020 02:31:38

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-28T12:00:53', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'da27d1ea-9f51-4ebb-a4d5-74fdf8229b33'	System	28 Nov 2020 17:01:11
User entered 'No (N)'	System	28 Nov 2020 17:01:11

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-28T12:00:58', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'da27d1ea-9f51-4ebb-a4d5-74fdf8229b33'	System	28 Nov 2020 17:01:11
User entered 'No (N)'	System	28 Nov 2020 17:01:11

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-11-28T12:01:04', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'da27d1ea-9f51-4ebb-a4d5-74fdf8229b33'	System	28 Nov 2020 17:01:11
User entered '28 Nov 2020 12:01:04'	System	28 Nov 2020 17:01:11

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-05T12:00:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd0eb9fb8-7bca-49c9-ba92-47f36ee3fc41'	System	05 Dec 2020 17:00:49
User entered 'No (N)'	System	05 Dec 2020 17:00:49

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-05T12:00:34', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd0eb9fb8-7bca-49c9-ba92-47f36ee3fc41'	System	05 Dec 2020 17:00:49
User entered 'No (N)'	System	05 Dec 2020 17:00:49

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-05T12:00:47', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'd0eb9fb8-7bca-49c9-ba92-47f36ee3fc41' User entered '05 Dec 2020 12:00:47'	System	05 Dec 2020 17:00:49
	System	05 Dec 2020 17:00:49

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-12T10:42:22', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '18a9ecaa-23ec-49cd-a3d7-bb76415ffec3' User entered 'No (N)'	System	12 Dec 2020 15:42:46
	System	12 Dec 2020 15:42:46

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-12T10:42:31', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '18a9ecaa-23ec-49cd-a3d7-bb76415ffec3' User entered 'No (N)'	System	12 Dec 2020 15:42:46
	System	12 Dec 2020 15:42:46

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-12T10:42:41', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '18a9ecaa-23ec-49cd-a3d7-bb76415ffec3' User entered '12 Dec 2020 10:42:41'	System	12 Dec 2020 15:42:46
	System	12 Dec 2020 15:42:46

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-19T12:29:24', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c6692f54-3163-4f7f-ab63-e20f629ed835'	System	19 Dec 2020 17:29:41
User entered 'No (N)'	System	19 Dec 2020 17:29:41

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-19T12:29:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c6692f54-3163-4f7f-ab63-e20f629ed835'	System	19 Dec 2020 17:29:41
User entered 'No (N)'	System	19 Dec 2020 17:29:41

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-19T12:29:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'c6692f54-3163-4f7f-ab63-e20f629ed835' User entered '19 Dec 2020 12:29:39'	System	19 Dec 2020 17:29:41
	System	19 Dec 2020 17:29:41

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-26T08:56:44', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '813c7232-50ce-4089-a2ce-ef65fde5590f' User entered 'No (N)'	System	26 Dec 2020 13:57:00
	System	26 Dec 2020 13:57:00

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-26T08:56:50', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '813c7232-50ce-4089-a2ce-ef65fde5590f' User entered 'No (N)'	System	26 Dec 2020 13:57:00
	System	26 Dec 2020 13:57:00

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2020-12-26T08:56:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '813c7232-50ce-4089-a2ce-ef65fde5590f' User entered '26 Dec 2020 08:56:55'	System	26 Dec 2020 13:57:00
	System	26 Dec 2020 13:57:00

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-02T12:01:12', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f677b28c-aea7-4572-944f-7fdd6702f255'	System	02 Jan 2021 17:01:39
User entered 'No (N)'	System	02 Jan 2021 17:01:39

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-02T12:01:25', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f677b28c-aea7-4572-944f-7fdd6702f255'	System	02 Jan 2021 17:01:39
User entered 'No (N)'	System	02 Jan 2021 17:01:39

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-02T12:01:31', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f677b28c-aea7-4572-944f-7fdd6702f255' User entered '02 Jan 2021 12:01:31'	System	02 Jan 2021 17:01:39
	System	02 Jan 2021 17:01:39

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-09T09:05:32', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1e498bd1-20ec-42be-9128-e2363f731cda' User entered 'No (N)'	System	09 Jan 2021 14:05:44
	System	09 Jan 2021 14:05:44

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-09T09:05:36', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1e498bd1-20ec-42be-9128-e2363f731cda' User entered 'No (N)'	System	09 Jan 2021 14:05:44
	System	09 Jan 2021 14:05:44

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-09T09:05:42', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1e498bd1-20ec-42be-9128-e2363f731cda' User entered '09 Jan 2021 09:05:42'	System	09 Jan 2021 14:05:44
	System	09 Jan 2021 14:05:44

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-16T12:02:18', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad2af16f-3c44-4ab5-ae28-6706ffdb0ce5' User entered 'Yes (Y)'	System	16 Jan 2021 17:03:29
	System	16 Jan 2021 17:03:29

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-16T12:02:33', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad2af16f-3c44-4ab5-ae28-6706ffdb0ce5'	System	16 Jan 2021 17:03:29
User entered 'No (N)'	System	16 Jan 2021 17:03:29

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-16T12:02:42', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad2af16f-3c44-4ab5-ae28-6706ffdb0ce5' User entered 'No (N)'	System	16 Jan 2021 17:03:29
	System	16 Jan 2021 17:03:29

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-16T12:02:52', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad2af16f-3c44-4ab5-ae28-6706ffdb0ce5' User entered 'No (N)'	System	16 Jan 2021 17:03:29

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-16T12:03:25', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ad2af16f-3c44-4ab5-ae28-6706ffdb0ce5' User entered '16 Jan 2021 12:03:25'	System	16 Jan 2021 17:03:29

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-23T12:02:49', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '751f548f-69df-4082-a154-2424c2dd1868'	System	23 Jan 2021 17:04:59
User entered 'No (N)'	System	23 Jan 2021 17:04:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-23T12:02:54', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '751f548f-69df-4082-a154-2424c2dd1868'	System	23 Jan 2021 17:04:59
User entered 'No (N)'	System	23 Jan 2021 17:04:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-23T12:02:58', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '751f548f-69df-4082-a154-2424c2dd1868' User entered '23 Jan 2021 12:02:58'	System	23 Jan 2021 17:04:59
	System	23 Jan 2021 17:04:59

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-28T10:19:27', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3f3f05fd-8952-4485-9d83-bcd7b0c6ac99'	System	28 Jan 2021 15:19:47
User entered 'No (N)'	System	28 Jan 2021 15:19:47

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-28T10:19:34', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3f3f05fd-8952-4485-9d83-bcd7b0c6ac99'	System	28 Jan 2021 15:19:47
User entered 'No (N)'	System	28 Jan 2021 15:19:47

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-01-28T10:19:42', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3f3f05fd-8952-4485-9d83-bcd7b0c6ac99' User entered '28 Jan 2021 10:19:42'	System	28 Jan 2021 15:19:47
	System	28 Jan 2021 15:19:47

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-04T10:44:55', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ee2894dc-880a-49b2-950d-a593812ce1b9' User entered 'No (N)'	System	04 Feb 2021 15:45:07
	System	04 Feb 2021 15:45:07

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-04T10:44:59', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ee2894dc-880a-49b2-950d-a593812ce1b9' User entered 'No (N)'	System	04 Feb 2021 15:45:07
	System	04 Feb 2021 15:45:07

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-04T10:45:03', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'ee2894dc-880a-49b2-950d-a593812ce1b9' User entered '04 Feb 2021 10:45:03'	System	04 Feb 2021 15:45:07
	System	04 Feb 2021 15:45:07

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-12T11:11:28', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '54c0283b-451a-4197-bfa2-881981ec01bc' User entered 'No (N)'	System	12 Feb 2021 16:11:44
	System	12 Feb 2021 16:11:44

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-12T11:10:48', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '54c0283b-451a-4197-bfa2-881981ec01bc' User entered 'No (N)'	System	12 Feb 2021 16:11:44
	System	12 Feb 2021 16:11:44

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-12T11:11:39', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '54c0283b-451a-4197-bfa2-881981ec01bc' User entered '12 Feb 2021 11:11:39'	System	12 Feb 2021 16:11:44
	System	12 Feb 2021 16:11:44

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-18T10:29:22', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '42e32e9d-e2da-4f79-854e-c20333c7c975'	System	18 Feb 2021 15:29:38
User entered 'No (N)'	System	18 Feb 2021 15:29:38

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-18T10:29:30', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '42e32e9d-e2da-4f79-854e-c20333c7c975'	System	18 Feb 2021 15:29:38
User entered 'No (N)'	System	18 Feb 2021 15:29:38

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-18T10:29:35', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '42e32e9d-e2da-4f79-854e-c20333c7c975'	System	18 Feb 2021 15:29:38
User entered '18 Feb 2021 10:29:35'	System	18 Feb 2021 15:29:38

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-25T12:18:30-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8616774a-6564-4b49-a6a1-954cc7cfe4fe'	System	25 Feb 2021 17:23:24
User entered 'No (N)'	System	25 Feb 2021 17:23:24

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-25T12:18:34-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8616774a-6564-4b49-a6a1-954cc7cfe4fe'	System	25 Feb 2021 17:23:24
User entered 'No (N)'	System	25 Feb 2021 17:23:24

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-02-25T12:18:42-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '8616774a-6564-4b49-a6a1-954cc7cfe4fe'	System	25 Feb 2021 17:23:24
User entered '25 Feb 2021 17:18:42'	System	25 Feb 2021 17:23:24

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-04T22:31:57-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1d145ad1-7304-47ca-a7c4-26fe469761a0'	System	05 Mar 2021 03:32:08
User entered 'No (N)'	System	05 Mar 2021 03:32:08

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-04T22:32:02-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1d145ad1-7304-47ca-a7c4-26fe469761a0'	System	05 Mar 2021 03:32:08
User entered 'No (N)'	System	05 Mar 2021 03:32:08

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-04T22:32:06-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '1d145ad1-7304-47ca-a7c4-26fe469761a0'	System	05 Mar 2021 03:32:08
User entered '04 Mar 2021 22:32:06'	System	05 Mar 2021 03:32:08

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-13T10:47:17-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '4cbf5de4-eda3-4efa-91b0-965d26f0a9df'	System	13 Mar 2021 15:47:31
User entered 'No (N)'	System	13 Mar 2021 15:47:31

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-13T10:47:24-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '4cbf5de4-eda3-4efa-91b0-965d26f0a9df'	System	13 Mar 2021 15:47:31
User entered 'No (N)'	System	13 Mar 2021 15:47:31

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-13T10:47:29-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '4cbf5de4-eda3-4efa-91b0-965d26f0a9df' User entered '13 Mar 2021 10:47:29'	System	13 Mar 2021 15:47:31

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-20T13:06:01-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '5ff037fd-ba11-4c89-8135-c73e532f8d16'	System	20 Mar 2021 17:07:43
User entered 'No (N)'	System	20 Mar 2021 17:07:43

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-20T13:06:05-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '5ff037fd-ba11-4c89-8135-c73e532f8d16'	System	20 Mar 2021 17:07:43
User entered 'No (N)'	System	20 Mar 2021 17:07:43

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-20T13:06:09-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '5ff037fd-ba11-4c89-8135-c73e532f8d16'	System	20 Mar 2021 17:07:43
User entered '20 Mar 2021 13:06:09'	System	20 Mar 2021 17:07:43

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-27T12:00:24-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '58156e46-ae5a-4dc4-82c0-b2c2d8d9de6c'	System	27 Mar 2021 16:00:56
User entered 'No (N)'	System	27 Mar 2021 16:00:56

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-27T12:00:31-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '58156e46-ae5a-4dc4-82c0-b2c2d8d9de6c'	System	27 Mar 2021 16:00:56
User entered 'No (N)'	System	27 Mar 2021 16:00:56

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-27T12:00:38-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '58156e46-ae5a-4dc4-82c0-b2c2d8d9de6c' User entered '27 Mar 2021 12:00:38'	System	27 Mar 2021 16:00:56
	System	27 Mar 2021 16:00:56

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-02T19:43:59-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '61a50fb8-d680-47a4-b26f-f3e125a2ea33'	System	02 Apr 2021 23:44:14
User entered 'No (N)'	System	02 Apr 2021 23:44:14

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-02T19:44:05-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '61a50fb8-d680-47a4-b26f-f3e125a2ea33'	System	02 Apr 2021 23:44:14
User entered 'No (N)'	System	02 Apr 2021 23:44:14

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-02T19:44:11-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '61a50fb8-d680-47a4-b26f-f3e125a2ea33'	System	02 Apr 2021 23:44:14
User entered '02 Apr 2021 19:44:11'	System	02 Apr 2021 23:44:14

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-09T11:59:28-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f1173f94-3b3a-4e62-b5a5-80a2fc1bb7cc'	System	09 Apr 2021 15:59:36
User entered 'No (N)'	System	09 Apr 2021 15:59:36

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-09T11:59:30-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f1173f94-3b3a-4e62-b5a5-80a2fc1bb7cc'	System	09 Apr 2021 15:59:36
User entered 'No (N)'	System	09 Apr 2021 15:59:36

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-09T11:59:33-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f1173f94-3b3a-4e62-b5a5-80a2fc1bb7cc'	System	09 Apr 2021 15:59:36
User entered '09 Apr 2021 11:59:33'	System	09 Apr 2021 15:59:36

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-15T06:12:28-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f57e7a6b-6c1c-4551-a942-ca031ebf2a03'	System	19 Apr 2021 18:18:08
User entered 'No (N)'	System	19 Apr 2021 18:18:08

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-15T06:12:33-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f57e7a6b-6c1c-4551-a942-ca031ebf2a03'	System	19 Apr 2021 18:18:08
User entered 'No (N)'	System	19 Apr 2021 18:18:08

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-15T06:12:41-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'f57e7a6b-6c1c-4551-a942-ca031ebf2a03'	System	19 Apr 2021 18:18:08
User entered '15 Apr 2021 06:12:41'	System	19 Apr 2021 18:18:08

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-22T11:29:57-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'b25cd724-5558-4efa-acd2-1c5d6d894c41'	System	22 Apr 2021 15:30:06
User entered 'No (N)'	System	22 Apr 2021 15:30:06

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-22T11:29:53-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'b25cd724-5558-4efa-acd2-1c5d6d894c41'	System	22 Apr 2021 15:30:06
User entered 'No (N)'	System	22 Apr 2021 15:30:06

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-22T11:30:02-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'b25cd724-5558-4efa-acd2-1c5d6d894c41'	System	22 Apr 2021 15:30:06
User entered '22 Apr 2021 11:30:02'	System	22 Apr 2021 15:30:06

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-29T06:13:10-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'edf10231-6c2b-4c39-8f1c-1d0ed5d4ae23'	System	29 Apr 2021 10:13:31
User entered 'No (N)'	System	29 Apr 2021 10:13:31

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Have you been exposed to someone with 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 (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-29T06:13:16-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'edf10231-6c2b-4c39-8f1c-1d0ed5d4ae23'	System	29 Apr 2021 10:13:31
User entered 'No (N)'	System	29 Apr 2021 10:13:31

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-04-29T06:13:25-04:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: 'edf10231-6c2b-4c39-8f1c-1d0ed5d4ae23'	System	29 Apr 2021 10:13:31
User entered '29 Apr 2021 06:13:25'	System	29 Apr 2021 10:13:31

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:32:28

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Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:32:28

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Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:32:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:32:28

US3662033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:32:28
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:32:28

US3662033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:21:09

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)	25 Apr 2021 13:01:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-04T22:32:15-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3641d933-befe-478c-998a-2319f1aafae3'	System	05 Mar 2021 03:32:22
User entered 'No (N)'	System	05 Mar 2021 03:32:22

US3662033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:21:09

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:01:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (554C01CC-FFE9-4AD3-B137-9F5A00A64BAA)', Time: '2021-03-04T22:32:20-05:00', User OID: 'PatientReportedOutcome (US3662033)', ODM File OID: '3641d933-befe-478c-998a-2319f1aafae3' User entered '04 Mar 2021 22:32:20'	System	05 Mar 2021 03:32:22
	System	05 Mar 2021 03:32:22

US3662033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Nov 2020 12:45:07

US3662033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '24 Nov 2020'	Angela Snyder (b) (4)	25 Nov 2020 12:45:07

US3662033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	25 Nov 2020 12:45:07

US3662033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Angela Snyder (b) (4)	25 Nov 2020 12:45:07

US3662033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Nov 2020 12:45:14

US3662033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 05:29:46
User entered 'I'	System	25 Nov 2020 12:45:14

US3662033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	29 Dec 2020 19:08:39

US3662033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '28 Dec 2020'	Brenda Miller (b) (4)	29 Dec 2020 19:08:39

US3662033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	29 Dec 2020 19:08:39

US3662033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	29 Dec 2020 19:08:39

US3662033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	29 Dec 2020 19:08:45

US3662033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User entered 'I'	System	29 Dec 2020 19:08:45

US3662033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Jan 2021 14:33:24

US3662033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '27 Jan 2021'	Angela Snyder (b) (4)	29 Jan 2021 14:33:24

US3662033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	29 Jan 2021 14:33:24

US3662033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Angela Snyder (b) (4)	29 Jan 2021 14:33:24

US3662033

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Jan 2021 14:33:30

US3662033

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User entered 'I'	System	29 Jan 2021 14:33:30

US3662033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Feb 2021 13:09:23

US3662033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '25 Feb 2021'	Angela Snyder (b) (4)	26 Feb 2021 13:09:23

US3662033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	26 Feb 2021 13:09:23

US3662033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Angela Snyder (b) (4)	26 Feb 2021 13:09:23

US3662033

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Feb 2021 13:09:29

US3662033

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:13
User entered 'I'	System	26 Feb 2021 13:09:29

US3662033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	06 Apr 2021 18:49:45
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '6 Apr 2021'	Angela Snyder (b) (4)	06 Apr 2021 18:49:45
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[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 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	06 Apr 2021 18:49:45
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User entered 'VISIT4'	System	06 Apr 2021 18:49:45

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '6 Apr 2021'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '12:43'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User entered '6 Apr 2021 12:43'	System	06 Apr 2021 18:50:29

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '97.9' F	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Other (Other)'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'infrared thermometer'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '57'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User entered 'bpm'	System	06 Apr 2021 18:50:29

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '16'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User entered 'breaths/min'	System	06 Apr 2021 18:50:29

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '150'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User entered 'mmHg'	System	06 Apr 2021 18:50:29

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '85'	Angela Snyder (b) (4)	06 Apr 2021 18:50:29
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User entered 'mmHg'	System	06 Apr 2021 18:50:29

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46

US3662033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46

US3662033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	06 Apr 2021 18:50:37
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	06 Apr 2021 18:50:37
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	06 Apr 2021 18:50:52
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '6 Apr 2021'	Angela Snyder (b) (4)	06 Apr 2021 18:50:52
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '12:53'	Angela Snyder (b) (4)	06 Apr 2021 18:50:52
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User entered '6 Apr 2021 12:53'	System	06 Apr 2021 18:50:52

US3662033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	06 Apr 2021 18:51:02
	(b) (4)	

US3662033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:18:46
User entered 'I'	System	06 Apr 2021 18:51:02

US3662033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Yes (Y)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:15:02
	(b) (4)	

US3662033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '27 Apr 2021'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:15:02
	(b) (4)	

US3662033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:15:02

US3662033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:15:02
	(b) (4)	

US3662033

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Apr 2021 17:15:08
	(b) (4)	

US3662033

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 17:15:08

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:21:09

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User closed query 'Please complete Generate Next COVID-19 Assessment page. ' (Site from CRA).	(b) (4)	
Query 'Please complete Generate Next COVID-19 Assessment page. ' answered with 'Data updated' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 17:59:35
User opened query 'Please complete Generate Next COVID-19 Assessment page. ' (Site from CRA).	Angela Snyder (b) (4)	06 Jan 2021 14:34:42
DataPoint Verified.	(b) (4)	
User entered '17 Oct 2020'	(b) (4), (b) (6)	05 Jan 2021 19:28:45
	(b) (4), (b) (6)	09 Nov 2020 18:36:56
	Brenda Miller (b) (4)	26 Oct 2020 19:06:14
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:21:09

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:36:56
User entered '17:00'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:06:14

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:21:09

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:27
User entered '17 Oct 2020 17:00'	System	26 Oct 2020 19:06:14

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:21:09

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:36:56
User entered 'Safety Call (Safety Call)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:06:14

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:21:09

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:36:56
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:06:14

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 1 (Day 1)'	Brenda Miller (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '08 Oct 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	08 Nov 2020 13:57:51
User entered '19 Oct 2020'	(b) (4) Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:21
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 00:36:13
User closed query 'should be Not Done per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:36:09
Query 'should be Not Done per source? Please confirm and update accordingly' answered with 'done' (Site from CRA).	michelle saemann (b) (4)	09 Nov 2020 19:39:30
User entered missing code ND - Not Done; reason for change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:39:23
User opened query 'should be Not Done per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 19:01:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:23
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4)	08 Nov 2020 13:57:51
User entered '99'	Brenda Miller (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:39:23
User entered empty.	System	08 Nov 2020 13:57:51
User entered '%'	System	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 00:36:18
User closed query 'should be Not Done per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:36:11
Query 'should be Not Done per source? Please confirm and update accordingly' answered with 'done' (Site from CRA).	michelle saemann (b) (4) (b) (4)	09 Nov 2020 19:39:36
User entered missing code ND - Not Done; reason for change Data Entry Error	michelle saemann (b) (4) (b) (4)	09 Nov 2020 19:39:23
User opened query 'should be Not Done per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 19:02:04
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:25
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:57:51
User entered '98.0' F	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User closed query 'Per D43 source note, subject has sinus congestion? Please review and update accordingly' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 03:11:44
Query 'Per D43 source note, subject has sinus congestion? Please review and update accordingly' answered with 'done. Will discuss sinus congestion with monitor. Thanks. ' (Site from CRA).	michelle saemann (b) (4) (b) (4)	09 Nov 2020 19:45:02
User opened query 'Per D43 source note, subject has sinus congestion? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 19:02:45
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 19:02:12
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:08:56

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 2 (Day 2)'	Brenda Miller (b) (4)	27 Oct 2020 17:52:46

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '09 Oct 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	08 Nov 2020 13:57:51
User entered '20 Oct 2020'	(b) (4) Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:09
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:40:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:40:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty; reason for change Data Entry	Brenda Miller (b) (4)	08 Nov 2020 13:57:51
Error	(b) (4)	
User entered '95'	Brenda Miller (b) (4)	27 Oct 2020 17:52:46
	(b) (4)	

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:40:24
User entered empty.	System	08 Nov 2020 13:57:51
User entered '%'	System	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:11
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:40:24
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:40:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty; reason for change Data Entry	Brenda Miller (b) (4)	08 Nov 2020 13:57:51
Error	(b) (4)	
User entered '97.8' F	Brenda Miller (b) (4)	27 Oct 2020 17:52:46
	(b) (4)	

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:52:46

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 3 (Day 3)'	Brenda Miller (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '10 Oct 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	08 Nov 2020 13:57:51
User entered '21 Oct 2020'	(b) (4) Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:21
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:40:43
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:40:43
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty; reason for change Data Entry	Brenda Miller (b) (4)	08 Nov 2020 13:57:51
Error	(b) (4)	
User entered '96'	Brenda Miller (b) (4)	27 Oct 2020 17:54:39
	(b) (4)	

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:40:43
User entered empty.	System	08 Nov 2020 13:57:51
User entered '%'	System	27 Oct 2020 17:54:39

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:22
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:40:43
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:40:43
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty; reason for change Data Entry	Brenda Miller (b) (4)	08 Nov 2020 13:57:51
Error	(b) (4)	
User entered '98.8' F	Brenda Miller (b) (4)	27 Oct 2020 17:54:39
	(b) (4)	

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

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Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 17:54:39

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 4 (Day 4)'	Brenda Miller (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '11 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:28
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:06
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:41:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:58:18
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:41:06
User entered empty.	System	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:29
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:06
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:41:06
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:58:18
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:18

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 5 (Day 5)'	Brenda Miller (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '12 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:35
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:20
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:41:20
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:58:41
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:41:20
User entered empty.	System	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:36
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:20
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:41:20
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:58:41
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:58:41

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 6 (Day 6)'	Brenda Miller (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '13 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:41
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:31
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:59:05
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:41:31
User entered empty.	System	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:42
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:31
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:41:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:59:05
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 7 (Day 7)'	Brenda Miller (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '14 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:47
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:43
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:59:28
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:41:43
User entered empty.	System	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:48
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:43
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:59:28
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:28

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 8 (Day 8)'	Brenda Miller (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '15 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:55
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:58
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:41:58
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:59:49
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:41:58
User entered empty.	System	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:56
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:41:58
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:41:58
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 13:59:49
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 13:59:49

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 9 (Day 9)'	Brenda Miller (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '16 Oct 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	08 Nov 2020 14:01:00
User entered '15 Oct 2020'	(b) (4) Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:32:02
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:44:02
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:44:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 14:00:27
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:44:02
User entered empty.	System	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:32:03
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:44:02
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:44:02
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 14:00:27
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:00:27

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 10 (Day 10)'	Brenda Miller (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '17 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:32:25
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:44:21
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 14:01:37
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:44:21
User entered empty.	System	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:32:27
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:44:21
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:44:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 14:01:37
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:01:37

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 11 (Day 11)'	Brenda Miller (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '18 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:32:33
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:44:34
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 19:44:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 14:03:05
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	09 Nov 2020 19:44:34
User entered empty.	System	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:32:35
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 19:44:34
User entered missing code ND - Not Done; reason for	(b) (4)	09 Nov 2020 19:44:34
change Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 14:03:05
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:01:14
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:03:05

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Brenda Miller (b) (4)	08 Nov 2020 14:13:01
User entered 'Day 13 (Day 13)'	(b) (4)	
	Brenda Miller (b) (4)	08 Nov 2020 14:04:56
	(b) (4)	

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:48:57
User entered '19 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:48:59
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:02
User entered '99'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:07
User entered '98.0' F	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:08
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:10
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:11
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:13
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:15
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:19
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:21
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:23
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:24
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:26
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:28
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:30
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:34
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:36
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:38
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:39
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:04:56

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 13 (Day 13)'	Brenda Miller (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:46
User entered '20 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:49:47
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:50:35
User entered '95'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:50:38
User entered '97.8' F	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:08
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:10
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:12
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:13
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:15
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:18
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:20
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:22
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:23
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:24
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:30
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:31
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:33
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:34
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:36
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:51:37
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:15:09

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Day 14 (Day 14)'	Brenda Miller (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:52:40
User entered '21 Oct 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:52:42
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:52:45
User entered '96'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User entered '%'	System	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:06
User entered '98.8' F	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:08
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:12
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:13
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:16
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:17
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:19
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:21
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:27
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:29
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:31
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:32
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:35
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:37
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:39
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:41
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:21:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:48
User entered 'None (None)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 14:17:52

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered '19 Oct 2020'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered '19 Oct 2020'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered empty.	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[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)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered 'No (N)' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:11:11
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:11:11
User entered 'UC HEALTH'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:44:51
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:11:11
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:21:09

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:47:59
User entered '0'	System	26 Oct 2020 19:09:59

US3662033

Folder: Covid-19 Assessment 17 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:21:09

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:48:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	Angela Snyder (b) (4)	06 Jan 2021 14:34:48

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:21:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User accepted default value 'Day 3 (Day 3)'	Brenda Miller (b) (4) (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:21:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:21:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:22:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'done' (Site from DM).	michelle saemann (b) (4) (b) (4)	12 Nov 2020 20:32:17
User entered '21 Oct 2020' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	12 Nov 2020 20:32:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:01:04
User entered empty.	Brenda Miller (b) (4) (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:21:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User accepted default value 'Day 5 (Day 5)'	Brenda Miller (b) (4) (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:21:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:21:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:21:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User accepted default value 'Day 7 (Day 7)'	Brenda Miller (b) (4) (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:21:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:21:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:21:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User accepted default value 'Day 9 (Day 9)'	Brenda Miller (b) (4) (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:21:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:21:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:21:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User accepted default value 'Day 14 (Day 14)'	Brenda Miller (b) (4) (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:21:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:21:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:21:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User accepted default value 'Day 21 (Day 21)'	Brenda Miller (b) (4) (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:21:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:21:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:21:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User accepted default value 'Day 28 (Day 28)'	Brenda Miller (b) (4) (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:21:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'NA (COVID-19 Negative) (NA)'	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:21:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	28 Oct 2020 12:31:15

US3662033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	26 Oct 2020 19:14:30

US3662033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '19 Oct 2020'	Brenda Miller (b) (4)	26 Oct 2020 19:14:30

US3662033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	26 Oct 2020 19:14:30

US3662033

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:40
User entered 'SICKD1'	System	26 Oct 2020 19:14:30

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '19 Oct 2020'	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '09:22'	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User entered '19 Oct 2020 09:22'	System	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '162.6' cm	(b) (4) Brenda Miller (b) (4)	26 Oct 2020 19:15:43
DataPoint set to visible.	(b) (4) System	26 Oct 2020 19:14:30

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '90.6' kg	(b) (4) Brenda Miller (b) (4)	26 Oct 2020 19:15:43
DataPoint set to visible.	(b) (4) System	26 Oct 2020 19:14:30

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '98.0' F	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Oral (Oral)'	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '58'	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User entered 'bpm'	System	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '16'	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User entered 'breaths/min'	System	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '150'	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User entered 'mmHg'	System	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '65'	Brenda Miller (b) (4)	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53
User entered 'mmHg'	System	26 Oct 2020 19:15:43

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 May 2021 04:15:53

US3662033

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:53

US3662033

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	26 Oct 2020 19:15:56

US3662033

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '19 Oct 2020'	Brenda Miller (b) (4)	26 Oct 2020 19:15:56

US3662033

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:21:09

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Brenda Miller (b) (4)	26 Oct 2020 19:16:18

US3662033

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:21:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '19 Oct 2020'	(b) (4) Brenda Miller (b) (4)	26 Oct 2020 19:16:18

US3662033

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 14:34:03

US3662033

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 14:34:03

US3662033

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	13 Jan 2021 14:34:03

US3662033

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

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 14:34:03

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:24:35
	(b) (4)	

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '0'	(b) (4) Angela Snyder (b) (4)	09 Mar 2021 18:49:30
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 07:45:12

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:24:35
	(b) (4)	

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Angela Snyder (b) (4)	09 Mar 2021 18:49:30
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	06 Mar 2021 07:45:12

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:24:35
	(b) (4)	

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	12 Jan 2021 18:24:35

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:51:44
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	12 Jan 2021 18:24:35
	(b) (4)	

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:51:44
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	12 Jan 2021 18:24:35
	(b) (4)	

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:24:35
	(b) (4)	

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '1'	System	12 Jan 2021 18:24:35

US3662033

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

Form: Unblinding

Generated On: 10 Jun 2021 09:21:09

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'I'	System	12 Jan 2021 18:24:35

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '162.56' cm	(b) (4) Angela Snyder (b) (4) (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '97.34' kg	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '36.83528'	System	13 Jan 2021 14:37:23
DataPoint set to visible.	System	12 Jan 2021 18:24:35

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '162.56' cm	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '97.34' kg	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '36.83528'	System	13 Jan 2021 14:37:23
DataPoint set to visible.	System	12 Jan 2021 18:24:35

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User accepted default value 'Pre-Dose (PREDOSE)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '13:13'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '12 Jan 2021 13:13'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '97.6' F	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Other (Other)'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'infrared thermometer'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '57'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'bpm'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '16'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'breaths/min'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '130'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'mmHg'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '71'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'mmHg'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '162.56' cm	(b) (4) Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '97.34' kg	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:21:09

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '36.83528'	System	13 Jan 2021 14:37:23
DataPoint set to visible.	System	12 Jan 2021 18:24:35

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User accepted default value 'Post-Dose (POSTDOSE)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '14:17'	(b) (4) Angela Snyder (b) (4)	13 Jan 2021 14:37:23
	(b) (4)	

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '12 Jan 2021 14:17'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '97.2' F	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Other (Other)'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'infrared thermometer'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '57'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'bpm'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '16'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'breaths/min'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '135'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'mmHg'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '77'	Angela Snyder (b) (4)	13 Jan 2021 14:37:23

US3662033

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'mmHg'	System	13 Jan 2021 14:37:23

US3662033

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 14:37:33

US3662033

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 14:37:33

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:56:23
	(b) (4)	

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:56:23
	(b) (4)	

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

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)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:56:23
	(b) (4)	

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'mRNA-1273'	System	12 Jan 2021 18:56:23
DataPoint set to visible.	System	12 Jan 2021 18:24:35

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:56:23

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '13:51'	(b) (4) MaKayla Bishop (b) (4)	12 Jan 2021 18:56:23
	(b) (4)	

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '12 Jan 2021 13:51'	System	12 Jan 2021 18:56:23

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	12 Jan 2021 18:56:23

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'ONCE'	System	12 Jan 2021 18:56:23

US3662033

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

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 18:56:23

US3662033

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 14:37:57

US3662033

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	(b) (4) Angela Snyder (b) (4)	13 Jan 2021 14:37:57

US3662033

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '13:25'	Angela Snyder (b) (4)	13 Jan 2021 14:37:57

US3662033

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '12 Jan 2021 13:25'	System	13 Jan 2021 14:37:57

US3662033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 14:38:16

US3662033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '12 Jan 2021'	Angela Snyder (b) (4)	13 Jan 2021 14:38:16

US3662033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '13:20'	Angela Snyder (b) (4)	13 Jan 2021 14:38:16

US3662033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:21:09

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered '12 Jan 2021 13:20'	System	13 Jan 2021 14:38:16

US3662033

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

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	13 Jan 2021 14:38:21

US3662033

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

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:21
User entered 'I'	System	13 Jan 2021 14:38:21

US3662033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Jan 2021 20:39:21

US3662033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '19 Jan 2021'	Angela Snyder (b) (4)	19 Jan 2021 20:39:21

US3662033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	19 Jan 2021 20:39:21

US3662033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Angela Snyder (b) (4)	19 Jan 2021 20:39:21

US3662033

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	19 Jan 2021 20:39:30

US3662033

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User entered 'I'	System	19 Jan 2021 20:39:30

US3662033

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User entered '1'	System	19 Jan 2021 20:39:30
DataPoint set to visible.	System	19 Jan 2021 20:39:30

US3662033

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	10 Feb 2021 16:57:47

US3662033

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '10 Feb 2021'	Angela Snyder (b) (4)	10 Feb 2021 16:57:47

US3662033

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	10 Feb 2021 16:57:47

US3662033

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'OLD29'	System	10 Feb 2021 16:57:47

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User accepted default value 'Pre-Dose (PREDOSE)'	Angela Snyder (b) (4) (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '10 Feb 2021'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '09:10'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered '10 Feb 2021 09:10'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '97.1' F	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Other (Other)'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'infrared thermometer'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '62'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'bpm'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '16'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'breaths/min'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '152'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mmHg'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '76'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mmHg'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User accepted default value 'Post-Dose (POSTDOSE)'	Angela Snyder (b) (4) (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '10 Feb 2021'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '10:01'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered '10 Feb 2021 10:01'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '97.6' F	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Other (Other)'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'infrared thermometer'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '57'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'bpm'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '16'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'breaths/min'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '131'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mmHg'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '87'	Angela Snyder (b) (4)	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mmHg'	System	10 Feb 2021 16:59:29

US3662033

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	10 Feb 2021 16:59:40

US3662033

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '10 Feb 2021'	Angela Snyder (b) (4)	10 Feb 2021 16:59:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

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)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mRNA-1273'	System	10 Feb 2021 14:35:40
DataPoint set to visible.	System	19 Jan 2021 20:39:30

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '10 Feb 2021'	MaKayla Bishop (b) (4)	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '09:31'	MaKayla Bishop (b) (4)	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered '10 Feb 2021 09:31'	System	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'ONCE'	System	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:21:09

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 14:35:40

US3662033

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	10 Feb 2021 16:59:45

US3662033

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'I'	System	10 Feb 2021 16:59:45

US3662033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Feb 2021 17:31:16

US3662033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '17 Feb 2021'	Angela Snyder (b) (4)	18 Feb 2021 17:31:16

US3662033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	18 Feb 2021 17:31:16

US3662033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:21:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Angela Snyder (b) (4)	18 Feb 2021 17:31:16

US3662033

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Feb 2021 17:31:23

US3662033

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:21:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User entered 'I'	System	18 Feb 2021 17:31:23

US3662033

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Mar 2021 18:48:13

US3662033

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '9 Mar 2021'	Angela Snyder (b) (4)	09 Mar 2021 18:48:13

US3662033

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	09 Mar 2021 18:48:13

US3662033

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:21:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User entered 'OLD57'	System	09 Mar 2021 18:48:13

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '9 Mar 2021'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '09:08'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User entered '9 Mar 2021 09:08'	System	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '97.6' F	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Other (Other)'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'infrared thermometer'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '58'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User entered 'bpm'	System	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '16'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User entered 'breaths/min'	System	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '154'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User entered 'mmHg'	System	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '76'	Angela Snyder (b) (4)	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User entered 'mmHg'	System	09 Mar 2021 18:49:02

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50

US3662033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:21:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50

US3662033

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'No (N)'	Angela Snyder (b) (4)	09 Mar 2021 18:49:09

US3662033

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:21:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered empty.	Angela Snyder (b) (4)	09 Mar 2021 18:49:09

US3662033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Mar 2021 18:49:24

US3662033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '9 Mar 2021'	Angela Snyder (b) (4)	09 Mar 2021 18:49:24

US3662033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User entered '09:12'	Angela Snyder (b) (4)	09 Mar 2021 18:49:24

US3662033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:21:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:50
User entered '9 Mar 2021 09:12'	System	09 Mar 2021 18:49:24

US3662033

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:21:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:06:58
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:13:33

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:09:08
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:00
User entered	System	11 Sep 2020 00:48:49
'USA-US088-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	11 Sep 2020 00:48:49

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:09:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Acute appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 17:25:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 17:25:42
Data point term sent to Coder	System	09 Sep 2020 17:24:51
User entered 'acute appendicitis'	michelle saemann (b) (4)	09 Sep 2020 17:24:09
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:12
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:16
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:18
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:19
User entered '8 Sep 2020'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:09:21
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Sep 2020 17:25:39
User entered empty; reason for change Data Entry Error	michelle saemann (b) (4)	09 Sep 2020 17:25:39
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Sep 2020 17:24:09
User entered '16:35'	michelle saemann (b) (4)	09 Sep 2020 17:24:09
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 17:25:39
User entered '8 Sep 2020 16:35'	System	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:22
User entered 'No (N)' reason for change: Data Entry Error	michelle saemann (b) (4)	20 Sep 2020 18:38:25
User entered 'Yes (Y)'	michelle saemann (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:09:24
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 22:11:54
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'resolved' (Site from Safety).	michelle saemann (b) (4)	20 Sep 2020 18:38:50
User entered '9 Sep 2020' reason for change: Data Entry Error	michelle saemann (b) (4)	20 Sep 2020 18:38:25
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 11:54:18
User entered empty.	michelle saemann (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:09:30
	(b) (4), (b) (6)	06 Oct 2020 03:37:37
User closed query 'Per DM Re-Query: Please note that end time is not required, unless end time is within 24 hours of dosing time. Please consider erasing this end time. Thank you' (Site from DM).		
Query 'Per DM Re-Query: Please note that end time is not required, unless end time is within 24 hours of dosing time. Please consider erasing this end time. Thank you' answered with 'resolved' (Site from DM).	michelle saemann (b) (4)	06 Oct 2020 00:44:52
User entered empty; reason for change Data Entry Error	michelle saemann (b) (4)	06 Oct 2020 00:44:44
User opened query 'Per DM Re-Query: Please note that end time is not required, unless end time is within 24 hours of dosing time. Please consider erasing this end time. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 16:13:28
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 16:12:37
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'resolved' (Site from System).	michelle saemann (b) (4)	20 Sep 2020 18:38:55
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	20 Sep 2020 18:38:25
User entered '21:43' reason for change: Data Entry Error	michelle saemann (b) (4)	20 Sep 2020 18:38:25
User entered empty.	michelle saemann (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 00:44:44
User entered '9 Sep 2020 21:43'	System	20 Sep 2020 18:38:25
User entered empty.	System	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:36
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:09:41
User entered '0'	michelle saemann (b) (4)	09 Sep 2020 17:24:09
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:42
User entered '0'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:44
User closed query 'PV Query: Please confirm if the subject was hospitalized for the event. If yes, please update serious criteria and provide hospital admission and discharge dates.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 22:11:57
Query 'PV Query: Please confirm if the subject was hospitalized for the event. If yes, please update serious criteria and provide hospital admission and discharge dates.' answered with 'resolved' (Site from Safety).	michelle saemann (b) (4) (b) (4)	20 Sep 2020 18:39:00
User entered '1' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	20 Sep 2020 18:38:25
User opened query 'PV Query: Please confirm if the subject was hospitalized for the event. If yes, please update serious criteria and provide hospital admission and discharge dates.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 11:54:42
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		09 Sep 2020 17:25:39
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		09 Sep 2020 17:25:39
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	09 Sep 2020 17:24:09
User entered '0'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:48
User entered '8 Sep 2020' reason for change: Data Entry Error	michelle saemann (b) (4)	20 Sep 2020 18:38:25
User entered empty.	michelle saemann (b) (4)	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:49
User entered '10 Sep 2020' reason for change: Data Entry Error	michelle saemann (b) (4)	20 Sep 2020 18:38:25
User entered empty.	michelle saemann (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:51
User entered 'No (N)' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	20 Sep 2020 18:38:25
User entered empty; reason for change Data Entry Error	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:25:39
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:53
User entered empty.	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

US3662033

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:09:55
User entered '0'	michelle saemann (b) (4)	09 Sep 2020 17:24:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:09:57
User entered '0'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:10:01
User entered 'I'	michelle saemann (b) (4)	09 Sep 2020 17:24:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:10:03
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:10:05
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:10:07
User entered 'None (NONE)'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:10:09
User entered '0'	michelle saemann (b) (4)	09 Sep 2020 17:24:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:10:15
User closed query 'Per CDM: Please confirm if any concomitant medications were given .If 'Yes' then please consider to update the details of medications related to this event within the event dates on concomitant medication page. or else clarify.Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:57:32
Query 'Per CDM: Please confirm if any concomitant medications were given .If 'Yes' then please consider to update the details of medications related to this event within the event dates on concomitant medication page. or else clarify.Thank you.' answered with 'Corrected data and recorded all medicatons' (Site from DM).	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:58:37
User entered '1' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:58:06
User opened query 'Per CDM: Please confirm if any concomitant medications were given .If 'Yes' then please consider to update the details of medications related to this event within the event dates on concomitant medication page. or else clarify.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:53:53
User entered '0'	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:10:17
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe (i.e. CT Scan per SAE Narrative). Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 08:00:13
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe (i.e. CT Scan per SAE Narrative). Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Concomitant procedures form completed' (Site from DM).	Brenda Miller (b) (4)	13 Oct 2020 13:51:25
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe (i.e. CT Scan per SAE Narrative). Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:17:20
User entered 'I'	michelle saemann (b) (4)	09 Sep 2020 17:24:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:10:21
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 22:12:03
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'resolved' (Site from Safety).	michelle saemann (b) (4)	20 Sep 2020 18:39:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	michelle saemann (b) (4)	20 Sep 2020 18:38:25
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 11:54:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	michelle saemann (b) (4)	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:10:25
User entered empty.	michelle saemann (b) (4) (b) (4)	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:10:28
User closed query 'Per DM CLR: SAE Narrative = CT. However, this information is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:50:29
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 18:42:59
Query 'Per DM CLR: SAE Narrative = CT. However, this information is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'done' (Site from DM).	Michelle Saemann (b) (4)	17 Oct 2020 16:46:38
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '9/9/2020 COVID test negative, Cepheid_ Xpert Xpress SARS-CoV-2 test_EUA ' (Site from Safety).	Michelle Saemann (b) (4)	17 Oct 2020 16:45:21
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:43:49
User opened query 'Per DM CLR: SAE Narrative = CT. However, this information is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:42:03
Query 'Per DM CLR: SAE Narrative = CT and IV antibiotics. However, these information were not recorded in the appropriate eCRF pages (e.g., CM and ConProc). Please review and ensure that these are captured in the appropriate eCRF. ' canceled (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:41:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = CT and IV antibiotics. However, these information were not recorded in the appropriate eCRF pages (e.g., CM and ConProc). Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:40:32
User closed query 'Per DM CLR: SAE NARRATIVE: IV antibiotics. However, this information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:43:03
Query 'Per DM CLR: SAE NARRATIVE: IV antibiotics. However, this information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Medications recorded on medications page' (Site from DM).	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:59:48
User opened query 'Per DM CLR: SAE NARRATIVE: IV antibiotics. However, this information is not captured in the appropriate eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:17:26
User closed query 'PV Query: Please confirm if paroxysmal atrial fibrillation was part of the subject's medical history. If yes, please consider adding it to the Medical History eCRF.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 22:12:10
User closed query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. ' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 22:12:06
Query 'PV Query: Please confirm if paroxysmal atrial fibrillation was part of the subject's medical history. If yes, please consider adding it to the Medical History eCRF.' answered with 'done' (Site from Safety).	michelle saemann (b) (4) (b) (4)	20 Sep 2020 18:42:39
Query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. ' answered with 'completed' (Site from Safety).	michelle saemann (b) (4) (b) (4)	20 Sep 2020 18:40:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT IS A 67YO FEMALE, H/O ATRIAL FIB (ELIQUIS - LAST DOSE TUES AM), PRESENTS WITH ACUTE RLQ ABDOMINAL PAIN X2 DAYS. LOW GRADE FEVER. +NAUSEA. EXAM AND CT C/W ACUTE APPENDICITIS ACUTE APPENDICITIS - PLAN OR FOR LAP APPY BUT GIVEN THERAPEUTIC ON ELIQUIS WILL PLAN FOR OR LIKELY END OF DAY WEDNESDAY. INFORMED CONSENT OBTAINED AFTER ALL RISKS/BENEFITS DISCUSSED INCLUDING RISK OF BLEEDING AND CONVERSION TO OPEN. IV ABX, NPO, ADMIT TO FLOOR. PARTICIPANT STILL IN ER, HAS NOT BEEN ADMITTED AT THIS TIME. Laparoscopic appendectomy performed 9/9/2020. Uncomplicated. Pathology: FINAL DIAGNOSIS: Appendix, appendectomy: - Severe acute appendicitis with acute serositis. - Negative for malignancy.'	michelle saemann (b) (4)	20 Sep 2020 18:40:43
reason for change: Data Entry Error Query 'PV Query: Please confirm if paroxysmal atrial fibrillation was part of the subject's medical history. If yes, please consider adding it to the Medical History eCRF.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 15:18:21
User opened query 'PV Query: Please confirm if paroxysmal atrial fibrillation was part of the subject's medical history. If yes, please consider adding it to the Medical History eCRF.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 14:26:45
Query 'PV Query: Please confirm if laparoscopic appendectomy was performed' canceled (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 14:26:35
User opened query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 11:55:29
User opened query 'PV Query: Please confirm if laparoscopic appendectomy was performed' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 11:55:13
User opened query 'PV Query: Please confirm if paroxysmal atrial fibrillation was part of the subject's medical history. If yes, please consider adding it to the Medical History eCRF.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 11:55:02

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Pt is a 67yo female, h/o atrial fib (eliquis - last dose Tues AM), presents with acute RLQ abdominal pain x2 days. Low grade fever. +nausea. Exam and CT c/w acute appendicitis Acute appendicitis - plan OR for lap appy but given therapeutic on eliquis will plan for OR likely end of day Wednesday. Informed consent obtained after all risks/benefits discussed including risk of bleeding and conversion to open. IV abx, NPO, admit to floor. Participant still in ER, has not been admitted at this time.'	michelle saemann (b) (4)	(b) (4) 09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Sep 2020 17:24:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:43
Data point term sent to Coder	System	09 Oct 2020 15:43:13
User entered 'ABDOMINAL PAIN POST-OP'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '11 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User entered empty.	System	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)' reason for change: Data Entry Error	Brenda Miller (b) (4)	09 Oct 2020 17:21:08
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '17 Sep 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	09 Oct 2020 17:21:08
User entered empty.	(b) (4) Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User entered empty.	System	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'None (NONE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'l'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:21:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User entered '0'	System	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41
User entered 'I'	System	09 Oct 2020 15:42:16

US3662033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:09:41

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:14:06
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:00:42
User entered	(b) (4), (b) (6)	12 Oct 2020 13:00:36
'USA-US088-2020-mRNA-1273-P301000001'		

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:14:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:56:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 15:56:21
Data point term sent to Coder	System	09 Oct 2020 15:55:40
User entered 'ABDOMINAL PAIN'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:14:02
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:14:00
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:13:58
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:52
User entered '08 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:50
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:47
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:45
User entered '10 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:13:41
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:39
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:29
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:27
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:25
User entered 'I'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:21
User entered '08 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:19
User entered '10 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:17
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:13:10
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:08
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:06
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:04
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:13:03
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:13:01
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:12:59
User entered 'None (NONE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:12:52
User entered 'I'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 06:28:02
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'ct abdomen and appendectomy has been recorded' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:31:03
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:34:10
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:12:49
User entered 'I'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:12:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Miller (b) (4)	09 Oct 2020 15:55:01
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:12:46
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:12:41
User entered 'PARTICIPANT DIAGNOSED WITH ACUTE APPENDICITIS. SAE COMPLETED FOR ACUTE APPRENDICITIS'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 15:55:01

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:06:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:06:28
Data point term sent to Coder	System	09 Oct 2020 16:06:01
User entered 'ABDOMINAL PAIN'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '07 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User entered empty.	System	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '08 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User entered empty.	System	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'None (NONE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'l'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User entered '0'	System	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55
User entered 'I'	System	09 Oct 2020 16:05:18

US3662033

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:55

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Low grade fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:11:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:11:24
Data point term sent to Coder	System	09 Oct 2020 16:08:13
User entered 'LOW GRADE FEVER 100.4'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '07 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User entered empty.	System	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User entered empty.	System	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'None (NONE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User closed query 'Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:39:34
Query 'Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' answered with 'done' (Site from DM).	michelle saemann (b) (4)	17 Oct 2020 16:53:55
User opened query 'Per CDM: Concomitant medication checkbox is selected However, no any medication recorded related to this event. Please confirm and update the medication on Concomitant medication form if it is given or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:54:33
User entered 'I'	Brenda Miller (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User entered '0'	System	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03
User entered '0'	System	09 Oct 2020 16:08:06

US3662033

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:03

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 06:28:21
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'post surgical fatigue, no illness per PI' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:35:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 09:28:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:48:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:48:21
Data point term sent to Coder	System	09 Oct 2020 17:28:11
User entered 'FATIGUE, POST SURGICAL'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User entered empty.	System	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)' reason for change: Data Entry Error	Brenda Miller (b) (4)	27 Oct 2020 15:14:50
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '07 Oct 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	27 Oct 2020 15:14:50
User entered empty.	(b) (4) Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User entered empty.	System	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'None (NONE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'l'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:14:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User entered '0'	System	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21
User entered '0'	System	09 Oct 2020 17:27:51

US3662033

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:21

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:53:38
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:28:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalised muscle aches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:35:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:35:08
Data point term sent to Coder	System	24 Nov 2020 19:34:19
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'disseminated' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:34:14
DataPoint Un-verified.	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:34:06
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:34:06
User entered 'MUSCLE ACHES, DISSEMINATED' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:34:06
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:35:46

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 18:18:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 18:18:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 13:46:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 13:46:30
Data point term sent to Coder	System	13 Oct 2020 13:45:11
User entered 'MUSCLE ACHES'	Brenda Miller (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:45:34
User closed query 'Per DM CLR-RQ: Site's response noted. Since this was not recorded on the subject's Diary, this may still be reported as AE but as Unsolicited event. Please review and update as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR-RQ: Site's response noted. Since this was not recorded on the subject's Diary, this may still be reported as AE but as Unsolicited event. Please review and update as appropriate. Otherwise, clarify.' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:13:54
DataPoint Un-verified.	Angela Snyder (b) (4) (b) (4)	06 Jan 2021 18:19:31
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	06 Jan 2021 18:19:21
User opened query 'Per DM CLR-RQ: Site's response noted. Since this was not recorded on the subject's Diary, this may still be reported as AE but as Unsolicited event. Please review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 18:10:14
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 15:46:46
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' answered with 'yes subject reported at follow up call, but not on ed diary ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:34:33

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:35:52
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '03 Oct 2020'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User entered empty.	System	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '03 Oct 2020'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User entered empty.	System	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Related (RELATED)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Related (RELATED)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:54:42
User closed query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 11:16:32
Query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'updated' (Site from DM).	michelle saemann (b) (4)	07 Dec 2020 22:25:54
DataPoint Un-verified.	michelle saemann (b) (4)	07 Dec 2020 22:25:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	michelle saemann (b) (4)	07 Dec 2020 22:25:48
User opened query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 19:24:39
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'None (NONE)'	Brenda Miller (b) (4)	13 Oct 2020 13:44:52

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:56:47
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' answered with 'Verbally reported. Solicited was changed to No in January prior to this query. Why is this being sent? ' (Site from DM).	michelle saemann (b) (4) (b) (4)	04 Feb 2021 18:08:12
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 08:14:15
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '1'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User entered '0'	System	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13
User entered '0'	System	13 Oct 2020 13:44:52

US3662033

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:13

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38

US3662033

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:46:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalised muscle aches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 18:11:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 18:11:50
Data point term sent to Coder	System	04 Feb 2021 18:11:06
DataPoint activated with code reason code Data required.	michelle saemann (b) (4) (b) (4)	04 Feb 2021 18:10:32
Data point term sent to Coder	System	23 Dec 2020 14:45:15
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4) (b) (4)	23 Dec 2020 14:44:38
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	25 Nov 2020 06:28:47
' (Site from DM).		
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	25 Nov 2020 06:28:45
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalised muscle aches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:34:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:34:04
Data point term sent to Coder	System	24 Nov 2020 19:33:15
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:32:58
' answered with 'no per pi no illness required' (Site from DM).		

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'disseminated' (Site from DM). DataPoint Un-verified.	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:32:39
	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:32:25
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:32:25
User entered 'MUSCLE ACHES, DISSEMINATED' reason for change: Data Entry Error DataPoint Verified.	MaKayla Bishop (b) (4) (b) (4) (b) (4), (b) (6)	24 Nov 2020 19:32:25 24 Nov 2020 19:07:12
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 09:29:38
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:36:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 18:03:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 18:03:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:47:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:47:41
Data point term sent to Coder	System	13 Oct 2020 13:47:13
User entered 'MUSCLE ACHES'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:46:25

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:46:02
DataPoint Un-verified.	michelle saemann (b) (4)	04 Feb 2021 18:12:06
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4) michelle saemann (b) (4)	04 Feb 2021 18:12:06
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4) (b) (4)	23 Dec 2020 14:44:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:46:25

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES ALL OVER BODY on 01 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES ALL OVER BODY on 01 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'subjected reported during safety call not entered properly on ediary ' (Site from DM).	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:47:22
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES ALL OVER BODY on 01 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	MaKayla Bishop (b) (4)	24 Nov 2020 19:33:27
User entered '29 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4), (b) (6)	17 Nov 2020 13:37:43
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User closed query 'Per CDM: Per page 31 of CCGs, This field is not required, unless start time is within 24 hours of dosing time. Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:42:16
Query 'Per CDM: Per page 31 of CCGs, This field is not required, unless start time is within 24 hours of dosing time. Please consider it to remove. Thank you. ' answered with 'Start time of 19:05 is within 24 hours from dose time of 09:24' (Site from DM).	Brenda Miller (b) (4)	23 Oct 2020 18:09:07
User opened query 'Per CDM: Per page 31 of CCGs, This field is not required, unless start time is within 24 hours of dosing time. Please consider it to remove. Thank you. ' (Site from DM).	(b) (4)	
User entered '19:05'	(b) (4), (b) (6)	23 Oct 2020 14:21:28
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
DataPoint activated with code reason code Data required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
User entered '29 Sep 2020 19:05'	System	13 Oct 2020 13:46:25

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered '01 Oct 2020'	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
User closed query 'Per CDM: Response noted. Per page 32 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Treatment date and time are 29SEP2020; 09:24 (24HR) and AE End date and time are 01OCT2020; 18:25 (24HR) which is more than 24 hours of IP dosing. Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:07:12
Query 'Data is required. Please provide.' answered with 'End time not required as it is not within 24 hours of dosing time' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 10:56:06
Query 'Per CDM: Response noted. Per page 32 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Treatment date and time are 29SEP2020; 09:24 (24HR) and AE End date and time are 01OCT2020; 18:25 (24HR) which is more than 24 hours of IP dosing. Please consider it to remove. Thank you. ' answered with 'Removed end time per query' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:56:04
User opened query 'Data is required. Please provide.' (Site from System).	Brenda Miller (b) (4)	27 Oct 2020 15:17:35
User entered empty; reason for change Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	27 Oct 2020 15:17:09
	System	27 Oct 2020 15:16:50
	Brenda Miller (b) (4)	27 Oct 2020 15:16:50

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'Per CDM: Response noted. Per page 32 of CCGs, This field is not required, unless End time is within 24 hours of dosing time (V2D29). Treatment date and time are 29SEP2020; 09:24 (24HR) and AE End date and time are 01OCT2020; 18:25 (24HR) which is more than 24 hours of IP dosing. Please consider it to remove. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:51:38
User closed query 'Per CDM: This Field is not required as This event started before dosing time. Please consider to remove this field. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:42:20
Query 'Per CDM: This Field is not required as This event started before dosing time. Please consider to remove this field. Thank you.' answered with 'This event started after dosing time of 09:24' (Site from DM).	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:13:19
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 18:11:56
User entered '18:25' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:11:56
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 18:10:46
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:10:46
User opened query 'Per CDM: This Field is not required as This event started before dosing time. Please consider to remove this field. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:22:44
User entered '18:25'	Brenda Miller (b) (4) (b) (4)	13 Oct 2020 13:46:25

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
DataPoint activated with code reason code Data required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
User entered empty.	System	27 Oct 2020 15:16:50
User entered '01 Oct 2020 18:25'	System	23 Oct 2020 18:11:56
User entered empty.	System	23 Oct 2020 18:10:46
User entered '01 Oct 2020 18:25'	System	13 Oct 2020 13:46:25

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Related (RELATED)'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
User entered 'Related (RELATED)'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:45:57
DataPoint Un-verified.	michelle saemann (b) (4)	04 Feb 2021 18:12:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
reason for change: Data Entry Error	michelle saemann (b) (4)	04 Feb 2021 18:12:06
DataPoint activated with code reason code Data	(b) (4)	
required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not	(b) (4)	
required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'None (NONE)'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint Verified.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	(b) (4)	
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint Verified.	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
	(b) (4), (b) (6)	24 Nov 2020 19:07:12
	Brenda Miller (b) (4)	13 Oct 2020 13:46:25
	(b) (4)	

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
DataPoint activated with code reason code Data required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
User entered '0'	System	13 Oct 2020 13:46:25

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
DataPoint activated with code reason code Data required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38
User entered '0'	System	13 Oct 2020 13:46:25

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Folder: Adverse Events

Form: Adverse Events (8)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:10:47
DataPoint activated with code reason code Data required.	Michelle Saemann (b) (4)	04 Feb 2021 18:10:32
DataPoint inactivated with code reason code Data not required.	Angela Snyder (b) (4)	23 Dec 2020 14:44:38

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:19:00
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	MaKayla Bishop (b) (4) (b) (4)	24 Nov 2020 19:36:00
' answered with 'yes, illness visit scheduled when the site was aware at safety call day 43' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	19 Nov 2020 09:31:51
' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:04:42
Data point term sent to Coder	System	23 Oct 2020 18:03:38
User entered 'SINUS CONGESTION'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '08 Oct 2020'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User entered empty.	System	23 Oct 2020 18:03:21

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)' reason for change: Data Entry Error	Brenda Miller (b) (4)	27 Oct 2020 15:13:25
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '12 Oct 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	27 Oct 2020 15:13:25
User entered empty.	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User entered empty.	System	23 Oct 2020 18:03:21

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

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Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'None (NONE)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'l'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:13:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User entered '0'	System	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28
User entered 'I'	System	23 Oct 2020 18:03:21

US3662033

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:28

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:18:43
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	MaKayla Bishop (b) (4)	24 Nov 2020 19:36:14
' answered with 'yes, illness visit scheduled when the site was aware at safety call day 43' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:12
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	19 Nov 2020 09:32:26
' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Postnasal drip - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:06:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 18:05:39
User entered 'POST NASAL DRIP'	Brenda Miller (b) (4)	23 Oct 2020 18:04:44
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '08 Oct 2020'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User entered empty.	System	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)' reason for change: Data Entry Error	Brenda Miller (b) (4)	27 Oct 2020 15:14:08
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '12 Oct 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	27 Oct 2020 15:14:08
User entered empty.	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User entered empty.	System	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Not Related (NOT RELATED)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'None (NONE)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'l'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:14:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:07:12
User entered empty.	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User entered '0'	System	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36
User entered 'I'	System	23 Oct 2020 18:04:44

US3662033

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:11:36

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 07:58:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 07:58:22
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	29 Apr 2021 22:53:45
Data point term sent to Coder	System	29 Apr 2021 17:19:48
User entered 'muscle spasm of lower back'	Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:19:31

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Yes (Y)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '19 Apr 2021'	Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 17:19:31

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Yes (Y)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 17:19:31

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '0'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '0'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '0'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:19:31

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '0'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '0'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:19:31

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '1'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:19:31

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:19:31
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 17:19:31

US3662033

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 17:19:31

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:01:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:01:52
Data point term sent to Coder	System	29 Apr 2021 17:20:49
User entered 'back pain'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '17 Apr 2021'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 17:20:32

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '19 Apr 2021'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 17:20:32

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:20:32
	(b) (4)	

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 17:20:32

US3662033

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:21:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 17:20:32

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:21:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:30:56

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: OLODATEROL HYDROCHLORIDE;Tiotropium Bromide Monohydrate, Productsynonym: STIOLTO RESPIMAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 14:21:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 14:21:20
Data point term sent to Coder	System	09 Oct 2020 15:18:30
Coding entries removed.	Brenda Miller (b) (4)	09 Oct 2020 15:17:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: OLODATEROL HYDROCHLORIDE;Tiotropium Bromide Monohydrate, Productsynonym: STIOLTO RESPIMAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:53:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 16:53:41
Data point term sent to Coder	System	02 Sep 2020 20:40:36
User entered 'Stiolo Respimat (mist)'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'COPD'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	23 Feb 2021 12:27:51
	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '2.5'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: CM dose unit other = MCG. Please review and determine if ug would be a more appropriate choice. If yes, please select ug from the list of drop down option under Dose unit as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 11:56:34
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	09 Oct 2020 15:19:54
Query 'Per DM CLR: CM dose unit other = MCG. Please review and determine if ug would be a more appropriate choice. If yes, please select ug from the list of drop down option under Dose unit as appropriate.' answered with 'Corrected to ug' (Site from DM).	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:17:31
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	09 Oct 2020 15:17:14
User entered 'ug (ug)' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:17:14
User opened query 'Per DM CLR: CM dose unit other = MCG. Please review and determine if ug would be a more appropriate choice. If yes, please select ug from the list of drop down option under Dose unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:00:42
User entered 'Other (OTHER)'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:40:22

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4)	09 Oct 2020 15:19:54
	(b) (4)	
User entered 'mcg'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:40:22

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: CM If route of administration is Other, specify = INHALATION SPRAY. Please review and determine if Respiratory (Inhalation) would be a more appropriate choice. If yes, please select Respiratory (Inhalation) from the list of drop down option under Route of administration as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 11:56:40
Query 'Per DM CLR: CM If route of administration is Other, specify = INHALATION SPRAY. Please review and determine if Respiratory (Inhalation) would be a more appropriate choice. If yes, please select Respiratory (Inhalation) from the list of drop down option under Route of administration as appropriate.' answered with 'Corrected data' (Site from DM).	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:18:29
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:17:57
User opened query 'Per DM CLR: CM If route of administration is Other, specify = INHALATION SPRAY. Please review and determine if Respiratory (Inhalation) would be a more appropriate choice. If yes, please select Respiratory (Inhalation) from the list of drop down option under Route of administration as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:00:43
User entered 'Other (OTHER)'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:40:22

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4)	09 Oct 2020 15:17:57
	(b) (4)	
User entered 'Inhalation spray'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '01 Jul 2019'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:40:22
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Brenda Miller (b) (4)	04 Sep 2020 13:35:44
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:40:22

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:40:22

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:40:22

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:40:22

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE ACETATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 06:04:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:04:37
Data point term sent to Coder	System	02 Sep 2020 20:42:44
User entered 'Flecainide Acetate'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:42:32

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Paroxysmal Atrial Fibrillation'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:42:32

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '50'	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'twice daily (BID)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '20 May 2019'	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:42:32

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:42:32
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Brenda Miller (b) (4)	03 Sep 2020 17:55:05
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:42:32

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 20:42:32

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:42:32

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:42:32

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Sep 2020 20:44:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:44:47
Data point term sent to Coder	System	02 Sep 2020 20:43:47
User entered 'Vitamin D'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:43:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Vitamin D Deficiency'	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '1000'	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'IU (IU)'	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:43:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '23 Apr 2019'	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:43:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Brenda Miller (b) (4)	03 Sep 2020 17:55:18
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:43:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:43:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:43:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:43:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Sep 2020 20:46:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:46:53
Data point term sent to Coder	System	02 Sep 2020 20:45:49
User entered 'Eliquis'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:44:57

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Paroxysmal Atrial Fibrillation'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:44:57

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '5'	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:44:57

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'twice daily (BID)'	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '07 Aug 2017'	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	03 Sep 2020 17:55:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:49:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 20:49:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	02 Sep 2020 20:49:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:44:57
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:44:57
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 20:44:57

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:44:57

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:44:57

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Sep 2020 20:47:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:47:44
Data point term sent to Coder	System	02 Sep 2020 20:46:52
User entered 'Sertraline'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:46:37

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Anxiety'	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '25'	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:46:37

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '01 Jan 2016'	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:46:37
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Brenda Miller (b) (4)	03 Sep 2020 17:55:47
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:46:37

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:46:37

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:46:37

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:46:37

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE, PRODUCTSYNONYM: HCTZ - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Sep 2020 20:48:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:48:47
Data point term sent to Coder	System	02 Sep 2020 20:47:56
User entered 'HCTZ'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:47:23

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Hypertension'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:47:23

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '25'	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'every other day (QOD)'	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '01 Jan 2010'	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	03 Sep 2020 17:56:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:50:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 20:50:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	02 Sep 2020 20:50:14
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:47:23
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:47:23
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:47:23

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 20:47:23

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:47:23

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Sep 2020 20:49:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:49:50
Data point term sent to Coder	System	02 Sep 2020 20:48:58
User entered 'Metoprolol'	Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:48:08

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Hypertension'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:48:08

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '25'	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	02 Sep 2020 20:48:08

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '01 Jan 2010'	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	03 Sep 2020 17:56:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:50:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 20:50:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	02 Sep 2020 20:50:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:48:08
User entered empty.	Brenda Miller (b) (4)	02 Sep 2020 20:48:08
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:48:08

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:48:08

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:48:08

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
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)	26 Jan 2021 13:49:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 13:49:08
Data point term sent to Coder	System	26 Jan 2021 13:48:36
Coding entries removed.	Angela Snyder (b) (4)	26 Jan 2021 13:47:51
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #24. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4)	26 Jan 2021 12:23:41
' canceled (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 12:23:12
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #24. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	26 Jan 2021 12:23:12
' (Site from DM).		
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)	09 Oct 2020 15:14:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 15:14:27
Data point term sent to Coder	System	09 Oct 2020 15:13:16
User entered 'TYLENOL'	Brenda Miller (b) (4)	09 Oct 2020 15:12:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
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) (6)	26 Feb 2021 16:18:42
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 'AE is in med history.' (Site from DM).	MaKayla Bishop (b) (4)	25 Feb 2021 14:35:43
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)	25 Feb 2021 03:39:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 17:02:24
Query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	26 Jan 2021 13:47:59
User entered 'generalized JOINT PAIN' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Jan 2021 13:47:51
User opened query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 12:19:44
User entered 'JOINT PAIN'	Brenda Miller (b) (4)	09 Oct 2020 15:12:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:16:30
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated 1000 mg per patient report' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:02:07
User entered '1000' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:01:49
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:31:35
User entered '2'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:12:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	30 Nov 2020 16:01:49
	(b) (4)	
User entered 'tablet (TABLET)'	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'as needed (PRN)'	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #24. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:13
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #24. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'log line 24 is from 09.07.2020. thanks ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 15:06:32
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med #24. Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:57:22
User entered '02 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:12:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:12:38
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
User closed query 'Per DM CL-RQ: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 09:31:12
Query 'Per DM CL-RQ: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please record this condition in AE eCRF and update this field to No. Else, provide clarification. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 12:16:43
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 12:16:34
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	23 Feb 2021 12:16:34
User opened query 'Per DM CL-RQ: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:41:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Joint pain in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:16:36

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Joint pain in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'yes' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:02:34
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Joint pain in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4)	26 Nov 2020 12:31:26
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:12:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:12:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:12:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 15:12:38

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFUROXIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:54:42
Data point term sent to Coder	System	09 Oct 2020 15:26:44
User entered 'CEFUROXIME'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:06
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:08
User entered 'APPENDICITIS'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:30
User entered '500'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:26
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:28
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:31
User entered 'twice daily (BID)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:33
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:16:54
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:21
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:40
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:38
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:36
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:34
User entered '12 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:31
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User entered '2'	System	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User entered '1'	System	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:56
User entered '804 (804)'	System	09 Oct 2020 15:26:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCODONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:18:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:18:40
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:05:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:30:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:30:29
Data point term sent to Coder	System	09 Oct 2020 15:27:48
User entered 'OXYCODONE HCI'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:47
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:49
User entered 'POST-OP ABDOMINAL PAIN'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:51
User entered '5'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:55
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:53
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:57
User entered 'as needed (PRN)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:05:59
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:01
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:03
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:17
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:19
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:36
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:38
User entered '13 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:06:39
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User entered empty.	System	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User entered empty.	System	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:00
User entered empty.	System	09 Oct 2020 15:27:09

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:17:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: PIPERACILLIN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:07:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:07:31
Data point term sent to Coder	System	09 Oct 2020 15:29:52
User entered 'PIPERACILLIN SODIUM'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:01
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:03
User entered 'APPENDICITIS'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:05
User entered '3.375'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:14
User entered 'g (g)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:15
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:17
User entered 'three times daily (TID)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:19
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:21
User entered 'Intravenous (INTRAVENOUS)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:22
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:25
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:30
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:32
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:34
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:37
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User entered '3'	System	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User entered '1'	System	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:27
User entered '804 (804)'	System	09 Oct 2020 15:29:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 02:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 02:29:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:35:25
User closed query 'please correct spelling - Ceftriaxone' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:35:23
Data point term sent to Coder	System	09 Nov 2020 21:20:49
Query 'please correct spelling - Ceftriaxone' answered with 'done' (Site from CRA).	michelle saemann (b) (4)	09 Nov 2020 21:20:45
DataPoint Un-verified.	michelle saemann (b) (4)	09 Nov 2020 21:20:07
Coding entries removed.	michelle saemann (b) (4)	09 Nov 2020 21:20:07
User entered 'CEFTRIAXONE SODIUM' reason for change: Data Entry Error	michelle saemann (b) (4)	09 Nov 2020 21:20:07
User opened query 'please correct spelling - Ceftriaxone' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 18:19:22
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:18:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 15:54:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 15:54:42
Data point term sent to Coder	System	09 Oct 2020 15:30:54

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'CEFRIAXONE SODIUM'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:18:56
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:31
User entered 'APPENDICITIS'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:33
User entered 'l'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:35
User entered 'g (g)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:36
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:38
User entered 'once (ONCE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:44
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:48
User entered 'Intravenous (INTRAVENOUS)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:50
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:52
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:54
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:19:56
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:00
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:02
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User entered empty.	System	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User entered empty.	System	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:32
User entered empty.	System	09 Oct 2020 15:30:25

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 08:04:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 08:04:17
Data point term sent to Coder	System	09 Oct 2020 15:31:55
User entered 'TORADOL'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:15
User entered 'ABDOMINAL PAIN'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:17
User entered '15'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:26
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:28
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:30
User entered 'once (ONCE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:31
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:33
User entered 'Intravenous (INTRAVENOUS)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:39
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:43
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:51
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:54
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:56
User entered '10 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:20:58
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User entered empty.	System	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User entered empty.	System	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:36
User entered empty.	System	09 Oct 2020 15:31:24

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GENERALIZED JOINT PAIN worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 15:46:40
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GENERALIZED JOINT PAIN worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'please see med indication. ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	18 Mar 2021 12:34:27
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GENERALIZED JOINT PAIN worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 02:53:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:10:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:10:27
Data point term sent to Coder	System	09 Oct 2020 15:32:57
User entered 'METRONIDAZOLE'	(b) (4), (b) (6)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:07
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:10
User entered 'APPENDICITIS'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:16
User entered '500'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:20
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:22
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:23
User entered 'three times daily (TID)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:27
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:30
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:34
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:36
User entered '09 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:38
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:40
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:45
User entered '12 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:21:52
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User entered '3'	System	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User entered '1'	System	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:40
User entered '804 (804)'	System	09 Oct 2020 15:32:20

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:44
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 18:22:05
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:21:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:58:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:58:27
Data point term sent to Coder	System	09 Oct 2020 15:33:58
User entered 'FENTANYL'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:45
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:47
User entered 'POST OP ABDOMINAL PAIN'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:49
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:17:25
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'correct dose per hospital records' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:44:06
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:29:29
User entered '12.5'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:53
User entered 'ug (ug)' reason for change: Data Entry Error	Brenda Miller (b) (4)	01 Nov 2020 15:29:47
User entered 'Other (OTHER)'	(b) (4) Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:55
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4)	01 Nov 2020 15:29:47
User entered 'mcg'	(b) (4) Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:56
User entered 'as needed (PRN)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:07:58
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:02
User entered 'Intravenous (INTRAVENOUS)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:05
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE condition. Please review and reconcile Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 06:40:28
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE condition. Please review and reconcile Con Med and AE start dates as appropriate. ' answered with 'AE Abdominal pain onset 08-sep-2020 - 10-sep-2020' (Site from DM).	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 14:33:30
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:08:11
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE condition. Please review and reconcile Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 13:02:58
User entered '09 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:13
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:16
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:17
User entered '09 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:08:19
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User entered empty.	System	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User entered empty.	System	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:32:44
User entered empty.	System	09 Oct 2020 15:33:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:23
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:58:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:58:27
Data point term sent to Coder	System	09 Oct 2020 15:35:00
User entered 'famotidine'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:25
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:29
User entered 'PRE-OP'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:33
User entered '20'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:46
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:48
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:49
User entered 'once (ONCE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:51
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:55
User entered 'Intravenous (INTRAVENOUS)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:22:57
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:04
User entered '09 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:06
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:08
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:09
User entered '09 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:12
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User entered empty.	System	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User entered empty.	System	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:18
User entered empty.	System	09 Oct 2020 15:34:48

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:27
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.	Coder Import (b) (4) (b) (4)	10 Oct 2020 07:05:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 07:05:23
Data point term sent to Coder	System	09 Oct 2020 15:36:01
User entered 'ZOFRAN'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:29
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:31
User entered 'PRE-OP'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:32
User entered '4'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:37
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:39
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:40
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:43
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:44
User entered 'Intravenous (INTRAVENOUS)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:49
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:51
User entered '09 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:23:53
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:24:04
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:24:06
User entered '09 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:24:08
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User entered '1'	System	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User entered '1'	System	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:22
User entered '804 (804)'	System	09 Oct 2020 15:35:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 15:38:24
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 Oct 2020 15:38:24
Data point term sent to Coder	System	09 Oct 2020 15:37:02
User entered 'ALBUTEROL'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'COPD'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '2'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'puff (PUFF)'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'once (ONCE)'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '09 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '09 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User entered empty.	System	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User entered empty.	System	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:26
User entered empty.	System	09 Oct 2020 15:36:45

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:39:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:39:27
Data point term sent to Coder	System	09 Oct 2020 15:38:04
User entered 'DILAUDID'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:24
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:26
User entered 'ABDOMINAL PAIN'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:27
User entered '0.5'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:29
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:31
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:40
User entered 'as needed (PRN)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:41
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:44
User entered 'Intravenous (INTRAVENOUS)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:46
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:49
User entered '08 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:53
User entered '0'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:25:55
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:26:05
User entered '08 Sep 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:26:08
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User entered empty.	System	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User entered empty.	System	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:33
User entered empty.	System	09 Oct 2020 15:37:53

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: BIFIDOBACTERIUM INFANTIS, PRODUCTSYNONYM: ALIGN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 17:45:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 17:45:30
Data point term sent to Coder	System	09 Oct 2020 17:17:50
User entered 'ALIGN PROBIOTIC'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:40
Query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' answered with 'done' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:41:28
User entered 'Yes (Y)' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:41:16
User opened query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:29:50
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'DIGESTIVE SUPPORT'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'I'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'tablet (TABLET)'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'once daily (QD)'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '10 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '27 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User entered '1'	System	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User entered '1'	System	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:33:56
User entered '804 (804)'	System	09 Oct 2020 17:17:03

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNA ALEXANDRINA EXTRACT, PRODUCTSYNONYM: SENNA CONCENTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Oct 2020 04:52:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:52:22
Data point term sent to Coder	System	09 Oct 2020 17:18:54
User entered 'SENNA CONCENTRATE'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'PROPHYLAXIS'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'I'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'tablet (TABLET)'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'as needed (PRN)'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '19 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '27 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User entered empty.	System	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User entered empty.	System	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:00
User entered empty.	System	09 Oct 2020 17:18:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
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.	(b) (4) Coder Import (b) (4) (b) (4)	09 Oct 2020 17:33:25
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 Oct 2020 17:33:25
Data point term sent to Coder	System	09 Oct 2020 17:32:22
User entered 'TYLENOL'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'MUSCLE ACHES'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '650'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'mg (mg)'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'as needed (PRN)'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '03 Oct 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '03 Oct 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User closed query 'Per DM CLR - RQ: Site's response noted. However, symptoms not recorded on eDiary are considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry to "NO" as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 05:54:51
Query 'Per DM CLR - RQ: Site's response noted. However, symptoms not recorded on eDiary are considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry to "NO" as appropriate.' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	10 Feb 2021 17:01:39
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	10 Feb 2021 17:01:31
User opened query 'Per DM CLR - RQ: Site's response noted. However, symptoms not recorded on eDiary are considered Unsolicited Adverse Reaction per Protocol section 8.3.4. Review and update entry to "NO" as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 03:11:04
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of MUSCLE ACHES in eDiary. Please note that this CM was given at Day 5 and AE has been recorded. Please consider to update 'Was this medication taken for solicited event' field to NO. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:17:51
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of MUSCLE ACHES in eDiary. Please note that this CM was given at Day 5 and AE has been recorded. Please consider to update 'Was this medication taken for solicited event' field to NO. Else, provide clarification. ' answered with 'pt forgot to record in ed diary ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:45:16

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of MUSCLE ACHES in eDiary. Please note that this CM was given at Day 5 and AE has been recorded. Please consider to update 'Was this medication taken for solicited event' field to NO. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:30:26
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User entered empty.	System	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User entered empty.	System	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:00
User entered empty.	System	09 Oct 2020 17:32:21

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
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.	(b) (4) Coder Import (b) (4)	09 Oct 2020 17:34:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 17:34:21
Data point term sent to Coder User entered 'TYLENOL'	System Brenda Miller (b) (4)	09 Oct 2020 17:33:25 09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'MUSCLE ACHES'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '650'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'mg (mg)'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'as needed (PRN)'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '29 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '0'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '01 Oct 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User entered empty.	System	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User entered empty.	System	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:04
User entered empty.	System	09 Oct 2020 17:33:05

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
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)	17 Oct 2020 16:55:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 16:55:30
Data point term sent to Coder	System	17 Oct 2020 16:54:18
User entered 'Tylenol'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary. Please note that this CM was given at Day 7 and AE has been recorded. Please review to update 'Was this medication taken for solicited event' field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:18:47
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary. Please note that this CM was given at Day 7 and AE has been recorded. Please review to update 'Was this medication taken for solicited event' field to No. Else, provide clarification.' answered with 'done ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	30 Nov 2020 16:48:16
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Fever in eDiary. Please note that this CM was given at Day 7 and AE has been recorded. Please review to update 'Was this medication taken for solicited event' field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:30:59
User entered 'fever/abdominal pain'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered '1000'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered 'mg (mg)'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered empty.	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered 'as needed (PRN)'	michelle saemann (b) (4)	17 Oct 2020 16:53:27
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered empty.	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered 'Oral (ORAL)'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered empty.	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered '07 Sep 2020'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered '0'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered '07 Sep 2020'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 22:23:40
User entered 'No (N)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	30 Nov 2020 16:48:10
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User entered empty.	System	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User entered empty.	System	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:05
User entered empty.	System	17 Oct 2020 16:53:27

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Oct 2020 18:02:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:02:38
Data point term sent to Coder	System	23 Oct 2020 18:01:34
User entered 'CLARITIN'	Brenda Miller (b) (4) (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'SINUS CONGESTION'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '10'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'mg (mg)'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'as needed (PRN)'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered empty.	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '08 Oct 2020'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '0'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)' reason for change: Data Entry Error	Brenda Miller (b) (4)	27 Oct 2020 15:12:01
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	27 Oct 2020 15:12:01
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	23 Oct 2020 18:01:33
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User entered 'No (N)'	Brenda Miller (b) (4)	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User entered empty.	System	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User entered empty.	System	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:09
User entered empty.	System	23 Oct 2020 18:01:33

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:55:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:55:47
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:47:22
Data point term sent to Coder	System	03 Feb 2021 17:58:04
User entered 'Omnipaque 350mg/ml'	michelle saemann (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered 'CT Contrast/procedure'	michelle saemann (b) (4)	03 Feb 2021 17:57:52
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered '125'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered 'mL (mL)'	michelle saemann (b) (4)	03 Feb 2021 17:57:52
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered empty.	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered 'once (ONCE)'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered empty.	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered 'Intravenous (INTRAVENOUS)'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered empty.	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered '8 Sep 2020'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered '0'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered '8 Sep 2020'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:22
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User entered empty.	System	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User entered empty.	System	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:35:34
User entered empty.	System	03 Feb 2021 17:57:52

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
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.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 21:59:20
Data point term sent to Coder	System	29 Apr 2021 17:17:44
User entered 'tylenol'	Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:17:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'muscle spasm of lower back'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:17:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '1000'	Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'twice daily (BID)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:17:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:17:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '19 Apr 2021'	Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Yes (Y)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:17:00
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 17:17:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 17:17:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 17:17:00

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 21:59:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 21:59:52
Data point term sent to Coder	System	29 Apr 2021 17:18:46
User entered 'robaxin'	Angela Snyder (b) (4)	29 Apr 2021 17:18:12

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'muscle spasm of lower back'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:18:12

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '500'	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Apr 2021 17:18:12

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '19 Apr 2021'	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
User entered 'Yes (Y)'	(b) (4) Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	29 Apr 2021 22:53:45
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Apr 2021 17:18:12
	(b) (4)	

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 17:18:12

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 17:18:12

US3662033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:21:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Apr 2021 17:18:12

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:21:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:58:22
User closed query 'Per CDM: Were any concomitant procedures performed is recorded as 'No' However, SAE Narrative of AE #1,(ACUTE APPENDICITIS) confirms that 'LAPAROSCOPIC APPENDECTOMY PERFORMED 9/9/2020..Kindly consider to record procedure 'LAPAROSCOPIC APPENDECTOMY' and its details in concomitant procedures pages. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 13:36:12
Query 'Per CDM: Were any concomitant procedures performed is recorded as 'No' However, SAE Narrative of AE #1,(ACUTE APPENDICITIS) confirms that 'LAPAROSCOPIC APPENDECTOMY PERFORMED 9/9/2020..Kindly consider to record procedure 'LAPAROSCOPIC APPENDECTOMY' and its details in concomitant procedures pages. Thank you. ' answered with 'Corrected to "yes", comcomitant procedure performed and completed Concomitant Procedures form' (Site from DM).	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:40:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:38:04
User opened query 'Per CDM: Were any concomitant procedures performed is recorded as 'No' However, SAE Narrative of AE #1,(ACUTE APPENDICITIS) confirms that 'LAPAROSCOPIC APPENDECTOMY PERFORMED 9/9/2020..Kindly consider to record procedure 'LAPAROSCOPIC APPENDECTOMY' and its details in concomitant procedures pages. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:45:08
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	04 Sep 2020 13:36:06

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:58:47
User entered '09 Sep 2020'	Brenda Miller (b) (4)	09 Oct 2020 17:38:34
	(b) (4)	

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:58:48
User entered 'LAPAROSCOPIC APPENDECTOMY' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:41:16
User entered 'APPENDECTOMY'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:38:34

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:58:50
User entered 'Adverse Event (AE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 17:38:34

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:21:09

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 19:58:52
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 17:38:34
	(b) (4)	

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:09

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:38
User entered '08 Sep 2020'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:46:25

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:38
User entered 'CT abdomen and pelvis with contrast'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:46:25

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:38
User entered 'Adverse Event (AE)'	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:46:25

US3662033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:21:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:48:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:47:38
User entered empty.	michelle saemann (b) (4) (b) (4)	17 Oct 2020 16:46:25

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered		
'USA-US088-2020-MRNA-1273-P301000001'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Un-reviewed for Safety.	System	20 Sep 2020 18:38:25
User entered 'Yes (Y)'	System	20 Sep 2020 18:38:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Carl'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Fichtenbaum'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered '231 Albert Sabin Way'	System	14 Sep 2020 21:56:00
User entered '200 Albert Sabin Way'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Cincinnati'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:00
User entered 'Ohio'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered '45267'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:52:55
User entered 'US' (non-conformant).	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Oct 2020 18:42:20
User entered '4'	System	12 Oct 2020 13:01:13
User entered '3'	System	06 Oct 2020 15:55:02
User entered '2'	System	20 Sep 2020 22:12:39
User entered '1'	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'USA-US088-2020-MRNA-1273-P301000001'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Un-reviewed for Safety.	System	20 Sep 2020 18:38:25
User entered 'Yes (Y)'	System	20 Sep 2020 18:38:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Carl'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Fichtenbaum'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered '231 Albert Sabin Way'	System	14 Sep 2020 21:56:00
User entered '200 Albert Sabin Way'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Cincinnati'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:00
User entered 'Ohio'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered '45267'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:52:55
User entered 'US' (non-conformant).	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Oct 2020 18:42:20
User entered '4'	System	12 Oct 2020 13:01:13
User entered '3'	System	06 Oct 2020 15:55:02
User entered '2'	System	20 Sep 2020 22:12:39
User entered '1'	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:21:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
User entered '10/Sep/2020 20:57'	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered		
'USA-US088-2020-MRNA-1273-P301000001'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Un-reviewed for Safety.	System	20 Sep 2020 18:38:25
User entered 'Yes (Y)'	System	20 Sep 2020 18:38:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Carl'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Fichtenbaum'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered '231 Albert Sabin Way'	System	14 Sep 2020 21:56:00
User entered '200 Albert Sabin Way'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Cincinnati'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:00
User entered 'Ohio'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered '45267'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:52:55
User entered 'US' (non-conformant).	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Oct 2020 18:42:20
User entered '4'	System	12 Oct 2020 13:01:13
User entered '3'	System	06 Oct 2020 15:55:02
User entered '2'	System	20 Sep 2020 22:12:39
User entered '1'	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:21:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
User entered '20/Sep/2020 18:12'	System	20 Sep 2020 22:12:39

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Oct 2020 15:54:49
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 22:12:39

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered		
'USA-US088-2020-MRNA-1273-P301000001'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Un-reviewed for Safety.	System	20 Sep 2020 18:38:25
User entered 'Yes (Y)'	System	20 Sep 2020 18:38:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Carl'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Fichtenbaum'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered '231 Albert Sabin Way'	System	14 Sep 2020 21:56:00
User entered '200 Albert Sabin Way'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Cincinnati'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:00
User entered 'Ohio'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered '45267'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:52:55
User entered 'US' (non-conformant).	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Oct 2020 18:42:20
User entered '4'	System	12 Oct 2020 13:01:13
User entered '3'	System	06 Oct 2020 15:55:02
User entered '2'	System	20 Sep 2020 22:12:39
User entered '1'	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:21:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
User entered '06/Oct/2020 15:55'	System	06 Oct 2020 15:55:02

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:01:00
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 15:55:02

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered		
'USA-US088-2020-MRNA-1273-P301000001'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Un-reviewed for Safety.	System	20 Sep 2020 18:38:25
User entered 'Yes (Y)'	System	20 Sep 2020 18:38:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Carl'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Fichtenbaum'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered '231 Albert Sabin Way'	System	14 Sep 2020 21:56:00
User entered '200 Albert Sabin Way'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Cincinnati'	michelle saemann (b) (4) (b) (4)	11 Sep 2020 12:30:06

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:00
User entered 'Ohio'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered '45267'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:52:55
User entered 'US' (non-conformant).	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Oct 2020 18:42:20
User entered '4'	System	12 Oct 2020 13:01:13
User entered '3'	System	06 Oct 2020 15:55:02
User entered '2'	System	20 Sep 2020 22:12:39
User entered '1'	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:21:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
User entered '12/Oct/2020 13:01'	System	12 Oct 2020 13:01:13

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 18:41:19
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 13:01:13

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered		
'USA-US088-2020-MRNA-1273-P301000001'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Un-reviewed for Safety.	System	20 Sep 2020 18:38:25
User entered 'Yes (Y)'	System	20 Sep 2020 18:38:25
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'No (N)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 00:57:23
User entered 'Yes (Y)'	System	11 Sep 2020 00:48:49

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Carl'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Fichtenbaum'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered '231 Albert Sabin Way'	System	14 Sep 2020 21:56:00
User entered '200 Albert Sabin Way'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered 'Cincinnati'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: User entered empty.	System	14 Sep 2020 21:56:00
User entered 'Ohio'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
User entered '45267'	michelle saemann (b) (4)	11 Sep 2020 12:30:06
	(b) (4)	

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 22:12:21
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:52:55
User entered 'US' (non-conformant).	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:21:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Oct 2020 18:42:20
User entered '4'	System	12 Oct 2020 13:01:13
User entered '3'	System	06 Oct 2020 15:55:02
User entered '2'	System	20 Sep 2020 22:12:39
User entered '1'	System	11 Sep 2020 00:57:30

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:21:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:07:09
User entered '19/Oct/2020 14:42'	System	19 Oct 2020 18:42:20

US3662033

Folder: SAE USA-US088-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:21:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 18:07:09
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 18:42:20