

US3662023 (Prod: Cincinnati CRS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:00:46

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US3662023

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 14:54:35

Generated On: 11 Aug 2021 23:00:46

Participant ID

US3662023

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

US3662023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

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

Visit date (dd MMM yyyy)	27 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3662023

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 14:54:45

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Date of Informed Consent (<i>dd MMM yyyy</i>)	27 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3662023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 14:54:45

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 14:54:45

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[Were any significant conditions reported?](#)

Yes ☒

No ☐

US3662023

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 14:54:45

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	15 JUL 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	15 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Condition	ANXIETY
Start date (dd MMM yyyy)	15 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 14:54:45

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Condition	HEARTBURN
Start date (dd MMM yyyy)	15 JUL 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 14:54:45

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Condition	INSOMNIA
Start date (dd MMM yyyy)	15 JUL 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)	JUL 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Condition	OTHER ARTHRITIS, BACK
Start date (dd MMM yyyy)	15 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	15 JUL 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:50
Height (xxx.x)	169.4 cm
Weight (xxx.x)	75.8 kg
BMI (xxx.x)	26.41450 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:54:45

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 14:54:45

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 14:54:45

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

What was the date of randomization? (dd MMM yyyy) 16 SEP 2020

What was the participant's randomization number? 190924

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) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Height	ND - Not Done
Weight	75.8 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Height	ND - Not Done
Weight	75.8 kg
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)	16 SEP 2020
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 10:50
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)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Height	ND - Not Done
Weight	75.8 kg
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)	16 SEP 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:50
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 11:19 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 11:19

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) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

10:47 (24 HR)

Collection date and time (derived)

16 SEP 2020 10:47

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:55	16 SEP 2020 10:55
Nasopharyngeal Swab 2	No		

US3662023

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 11:53

PC Open Date & Time

16 SEP 2020 11:39

PC Close Date & Time

16 SEP 2020 14:09

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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

97.3 °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	17 SEP 2020 06:57
PC Open Date & Time	16 SEP 2020 15:04
PC Close Date & Time	17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 08:13

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

18 SEP 2020 12:14

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 16:13

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 08:47

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

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

97.1 °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

21 SEP 2020 13:25

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

98.3 °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

22 SEP 2020 13:10

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 11:55

PC Open Date & Time

16 SEP 2020 11:39

PC Close Date & Time

16 SEP 2020 14:09

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 06:58

PC Open Date & Time

16 SEP 2020 15:04

PC Close Date & Time

17 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 08:14

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

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

18 SEP 2020 12:15

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

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

19 SEP 2020 16:13

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 08:48

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

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

21 SEP 2020 13:26

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

22 SEP 2020 13:11

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 11:55
PC Open Date & Time	16 SEP 2020 11:39
PC Close Date & Time	16 SEP 2020 14:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 06:59
PC Open Date & Time	16 SEP 2020 15:04
PC Close Date & Time	17 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 08:15
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:16
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 16:14
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

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)

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 08:48
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 13:27
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 24 SEP 2020 08:40

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 24 SEP 2020 13:12

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 10

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 ☐

PC Time Stamp 26 SEP 2020 07:28

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 08:40
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 13:12
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 SEP 2020 07:28
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3662023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

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

Visit date (dd MMM yyyy)	14 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

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)	14 OCT 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 10:32
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

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)	14 OCT 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 11:50
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3662023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

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) 14 OCT 2020

What was the treatment time? (00:00-23:59) 11:17 (24 HR)

Treatment Date and Time (derived) 14 OCT 2020 11:17

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

US3662023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

10:55 (24 HR)

Collection date and time (derived)

14 OCT 2020 10:55

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Collection date (dd MMM yyyy)			14 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:50	14 OCT 2020 10:50
Nasopharyngeal Swab 2	No		

US3662023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

14 OCT 2020 11:43

PC Open Date & Time

14 OCT 2020 11:37

PC Close Date & Time

14 OCT 2020 14:07

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 97.7 °F

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

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

PC Time Stamp	14 OCT 2020 20:56
PC Open Date & Time	14 OCT 2020 15:02
PC Close Date & Time	15 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 13:09

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 14:50

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

18 OCT 2020 08:20

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 07:43

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 13:03

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 12:02

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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

14 OCT 2020 11:44

PC Open Date & Time

14 OCT 2020 11:37

PC Close Date & Time

14 OCT 2020 14:07

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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

14 OCT 2020 20:56

PC Open Date & Time

14 OCT 2020 15:02

PC Close Date & Time

15 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

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

15 OCT 2020 13:09

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

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

16 OCT 2020 14:51

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

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

18 OCT 2020 08:20

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

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

19 OCT 2020 07:43

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

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

19 OCT 2020 13:03

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

20 OCT 2020 12:02

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 11:44
PC Open Date & Time	14 OCT 2020 11:37
PC Close Date & Time	14 OCT 2020 14:07

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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

No ☒

Yes ☐

PC Time stamp	14 OCT 2020 20:57
PC Open Date & Time	14 OCT 2020 15:02
PC Close Date & Time	15 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 13:10
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 14:51
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 08:21
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 07:44
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 13:04
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

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 ☒

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 12:03
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3662023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3662023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	10:07 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 10:07
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3662023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

10:13 (24 HR)

Collection date and time (derived)

12 NOV 2020 10:13

US3662023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:46

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 NOV 2020 11:10:00
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 NOV 2020 21:43:18
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 NOV 2020 12:14:34
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

04 DEC 2020 12:02:36

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 14:25:52
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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	18 DEC 2020 19:08:04
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Patient Cloud Open Date & Time	25 DEC 2020 00:01
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Patient Cloud Close Date & Time	29 DEC 2020 23:59
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US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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	04 JAN 2021 11:17:06
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 JAN 2021 08:58:09
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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	15 JAN 2021 10:12:41
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 08:29:22

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 00:02:00

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 07:59:25
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 06:14:31
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 09:15:08

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 00:02:00
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

09 MAR 2021 08:27:28

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 23:44:02
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 13:11:57
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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	26 MAR 2021 00:01:48
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 14:09:15
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

16 APR 2021 13:30:53

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

27 APR 2021 16:50:00

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 16:52:24
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 250

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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°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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 264

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 418

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

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

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

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

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

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

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 425

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

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

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

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

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

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

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Patient Cloud Open Date & Time	03 DEC 2021 00:01
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Patient Cloud Close Date & Time	07 DEC 2021 23:59
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US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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08 MAR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 642

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

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

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

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

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

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

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐ 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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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°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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

DAY 796

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

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

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

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

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

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

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

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

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3662023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:00:46

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		05 MAR 2021 08:22:13

US3662023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 19:02:13

Generated On: 11 Aug 2021 23:00:46

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

Visit date (dd MMM yyyy)	16 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
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US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 19:02:13

Generated On: 11 Aug 2021 23:00:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 APR 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	16 APR 2021 12:15
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 19:02:13

Generated On: 11 Aug 2021 23:00:46

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.

US3662023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 19:02:13

Generated On: 11 Aug 2021 23:00:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 APR 2021

Collection time (00:00-23:59)

12:25 (24 HR)

Collection date and time (derived)

16 APR 2021 12:25

US3662023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 19:02:13

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Date of Contact	8 JAN 2021
Time of Contact	09:08
Date and Time of Contact (derived)	8 JAN 2021 09:08
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>

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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	7 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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	8 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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 (3)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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 (6)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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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Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (8)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input 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 08 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 14:54:44

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

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Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (10)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
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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Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (11)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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 (12)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

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Generated On: 11 Aug 2021 23:00:46

	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

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Form: Symptom Log (12)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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 (13)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (13)

Data signed: (b) (4) 22 Feb 2021 14:54:44

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

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Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (14)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

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Form: Symptom Log (15)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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 (16)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Symptom Day

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

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

	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"/>

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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"/>

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Date of Visit	8 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	8 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 21:44:25

Generated On: 11 Aug 2021 23:00:46

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date 14 JAN 2021

End Date 15 JAN 2021

Oxygen Saturation 93 %

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 21:44:25

Generated On: 11 Aug 2021 23:00:46

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

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 08 Apr 2021 21:44:25

Generated On: 11 Aug 2021 23:00:46

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

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

Start Date

End Date

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Date of Contact	8 JAN 2021
Time of Contact	09:08
Date and Time of Contact (derived)	8 JAN 2021 09:08
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>

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Date of Visit	8 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	8 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	UC HEALTH LAB
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

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

If Yes, provide:

Start Date _____
End Date _____
Respiratory Rate _____

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

If Yes, provide:

Start Date _____
End Date _____
Heart Rate _____

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

If Yes, provide:

Start Date _____
End Date _____
Oxygen Saturation _____

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

If Yes, provide:

Start Date _____
End Date _____
PaO₂ _____

Did the subject have Respiratory failure? Yes ☐
No ☐

Start Date _____

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

Start Date _____

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Hepatic Dysfunction? Yes ☐
No ☐

Start Date

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☐

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

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

Start Date

End Date

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 28 Apr 2021 13:38:49

Generated On: 11 Aug 2021 23:00:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 JAN 2021
Day 5	Yes	12 JAN 2021
Day 7	Yes	14 JAN 2021
Day 9	Yes	15 JAN 2021
Day 14	Yes	21 JAN 2021
Day 21	Yes	28 JAN 2021
Day 28	Yes	5 FEB 2021

US3662023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 JAN 2021
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 11:10
Height (xxx.x)	168.91 cm
Weight (xxx.x)	71.39 kg
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 JAN 2021

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

US3662023

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 JAN 2021

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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	SICKD28

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 FEB 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 08:15
Height (xxx.x)	171.25 cm
Weight (xxx.x)	72.03 kg
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)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3662023

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

5 FEB 2021

US3662023

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3662023

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Date of updated informed consent (<i>dd MMM yyyy</i>)	5 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>)	5 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

US3662023

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Height	169.16 cm
Weight	72.75 kg
BMI (xxx.x)	25.42363

US3662023

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Height	169.16 cm
Weight	72.75 kg
BMI (xxx.x)	25.42363
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)	5 JAN 2021
Time of assessment (00:00-23:59)	07:57 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 07:57
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3662023

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Height	169.16 cm
Weight	72.75 kg
BMI (xxx.x)	25.42363
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)	5 JAN 2021
Time of assessment (00:00-23:59)	09:04 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 09:04
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)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3662023

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3662023

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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) 5 JAN 2021

What was the treatment time? (00:00-23:59) 08:34 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 08:34

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

US3662023

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 JAN 2021

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

5 JAN 2021 08:25

US3662023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 JAN 2021
Collection time (00:00 - 23:59)	08:20
Collection Date and Time (derived)	5 JAN 2021 08:20

US3662023

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

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

OL DAY 8 SAFETY CALL NOT
DONE. PATIENT IN
CONVALESCENCE PHASE

If Contact Not Made, please provide Comments

US3662023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

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

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Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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)	5 FEB 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 08:15
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)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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)	5 FEB 2021
Time of assessment (00:00-23:59)	09:34 (24 HR)
Vital Signs Date and Time (derived)	5 FEB 2021 09:34
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3662023

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 FEB 2021

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

US3662023

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

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) 5 FEB 2021

What was the treatment time? (00:00-23:59) 09:04 (24 HR)

Treatment Date and Time (derived) 5 FEB 2021 09:04

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

US3662023

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:44

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:54:45

Generated On: 11 Aug 2021 23:00:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662023

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 MAR 2021
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 08:09
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662023

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

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.

US3662023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 MAR 2021

Collection time (00:00-23:59)

08:16 (24 HR)

Collection date and time (derived)

5 MAR 2021 08:16

US3662023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 14:54:35

Generated On: 11 Aug 2021 23:00:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 18 Mar 2021 21:17:22

Generated On: 11 Aug 2021 23:00:46

AEID	USA-US088-2021-MRNA-1273-P30 1000003
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	7 JAN 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)	16 JAN 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"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 18 Mar 2021 21:17:22

Generated On: 11 Aug 2021 23:00:46

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 18 Mar 2021 21:17:22

Generated On: 11 Aug 2021 23:00:46

AEID

Adverse event

DECREASED APPETITE

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)

25 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 JAN 2021

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) 18 Mar 2021 21:17:22

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 18 Mar 2021 21:17:22

Generated On: 11 Aug 2021 23:00:46

AEID

Adverse event

PAIN AT INJECTION SITE,
IPSILATERAL TO STUDY MED
INJECTION

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) 22 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) 24 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 ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 18 Mar 2021 21:17:22

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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 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	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)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 14:54:35

Generated On: 11 Aug 2021 23:00:46

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

Yes ☒

No ☐

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

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

	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)	11 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 OCT 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 (2)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 FEB 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)		3
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) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication LAMOTRIGINE

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 FEB 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)	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) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JUL 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication TRAZODONE HCl

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JUL 2016
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 JUL 2002
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"/>

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

	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)		1 NOV 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

Name of Medication CAPSAICIN 0.1%

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS, BACK PAIN,
OSTEOARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3662023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Feb 2021 14:54:43

Generated On: 11 Aug 2021 23:00:46

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 FEB 2021	ABNORMAL ULTRASOUND	Diagnostic	

US3662023

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:00:46

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

US3662023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:00:46

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 ☐

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

SAEID	USA-US088-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

SAEID	USA-US088-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	11/JAN/2021 15:56
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

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

SAEID	USA-US088-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	22/JAN/2021 13:33
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

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Mar 2021 21:17:23

Generated On: 11 Aug 2021 23:00:46

SAEID	USA-US088-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	15/MAR/2021 16:16
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

US3662023 (Prod: Cincinnati CRS)

US3662023

Form: Participant Creation

Generated On: 11 Aug 2021 23:00:46

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'US3662023'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:25:54

US3662023

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User closed query 'Per CDM: Please review and if confirmed that 'Visit 1 Day 1' was performed, then please complete all applicable forms on 'Visit 1 Day 1'. Else comment to explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 14:37:51
Query 'Per CDM: Please review and if confirmed that 'Visit 1 Day 1' was performed, then please complete all applicable forms on 'Visit 1 Day 1'. Else comment to explain.' answered with 'Visit Day 1 not yet completed' (Site from DM).	Brenda Miller (b) (4) (b) (4)	14 Sep 2020 13:34:27
User opened query 'Per CDM: Please review and if confirmed that 'Visit 1 Day 1' was performed, then please complete all applicable forms on 'Visit 1 Day 1'. Else comment to explain.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 11:02:40
User entered 'Yes (Y)'	Sarah Trentman (b) (4) (b) (4)	28 Aug 2020 18:45:04

US3662023

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:25:55

US3662023

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[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 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Clinic (Clinic)'	Sarah Trentman (b) (4)	28 Aug 2020 18:45:04

US3662023

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'SCRN'	System	28 Aug 2020 18:45:04

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:25:56

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '65'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'YEARS'	System	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '65'	System	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Male (M)'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'I'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:47:15

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '27 Aug 2020'	Sarah Trentman (b) (4)	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'Aug 2020'	System	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '2020'	System	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Amendment 2 (2)'	Sarah Trentman (b) (4)	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:49:28

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 16:25:55

US3662023

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:00:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'I'	System	28 Aug 2020 18:49:34

US3662023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 23:00:46

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	28 Aug 2020 18:49:34

US3662023

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 23:00:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	28 Aug 2020 18:50:20

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:08:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:08:56
Data point term sent to Coder	System	25 Sep 2020 17:03:43
Coding entries removed.	Brenda Miller (b) (4)	25 Sep 2020 17:03:24
User entered 'HYPERTENSION' reason for change: Data Entry Error	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Brenda Miller (b) (4)	25 Sep 2020 17:03:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:52:42
Data point term sent to Coder	(b) (4)	
User entered 'Hypertenstion'	Coder Import (b) (4)	28 Aug 2020 18:52:42
	(b) (4)	
	System	28 Aug 2020 18:51:25
	Sarah Trentman (b) (4)	28 Aug 2020 18:51:12
	(b) (4)	

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '15 Jul 2009'	Sarah Trentman (b) (4)	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'Jul 2009'	System	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '2009'	System	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	28 Aug 2020 18:51:12

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:08:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:08:53
Data point term sent to Coder	System	25 Sep 2020 17:02:42
Coding entries removed.	Brenda Miller (b) (4)	25 Sep 2020 17:02:36
User entered 'BIPOLAR DISORDER' reason for change: Data Entry Error	Brenda Miller (b) (4)	25 Sep 2020 17:02:36
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar depression - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:52:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 18:52:43
Data point term sent to Coder	System	28 Aug 2020 18:52:29
User entered 'bipolar depression'	Sarah Trentman (b) (4)	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '15 Feb 2020' reason for change: Data Entry Error	(b) (4)	
	Brenda Miller (b) (4)	25 Sep 2020 17:02:36
User entered '15 Jul 2016'	(b) (4)	
	Sarah Trentman (b) (4)	28 Aug 2020 18:52:10
	(b) (4)	

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'Feb 2020'	System	25 Sep 2020 17:02:36
User entered 'Jul 2016'	System	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '2020'	System	25 Sep 2020 17:02:36
User entered '2016'	System	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	28 Aug 2020 18:52:10

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 19:06:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 19:06:45
Data point term sent to Coder	System	24 Sep 2020 19:02:29
User entered 'ANXIETY'	Brenda Miller (b) (4)	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '15 Feb 2020'	Brenda Miller (b) (4)	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Brenda Miller (b) (4)	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Brenda Miller (b) (4)	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'Feb 2020'	System	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '2020'	System	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	24 Sep 2020 19:01:29

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Sep 2020 17:09:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:09:01
Data point term sent to Coder	System	25 Sep 2020 17:04:45
User entered 'HEARTBURN'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '15 Jul 2018'	Brenda Miller (b) (4)	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'Jul 2018'	System	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '2018'	System	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	25 Sep 2020 17:04:06

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:09:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 17:09:04
Data point term sent to Coder	System	25 Sep 2020 17:04:45
User entered 'INSOMNIA'	Brenda Miller (b) (4)	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '15 Jul 2016'	Brenda Miller (b) (4)	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'Jul 2016'	System	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '2016'	System	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	25 Sep 2020 17:04:25

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Spondyloarthropathies, PT: Spondylitis, LLT: Back arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 09:49:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 09:49:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	22 Feb 2021 14:54:47
Data point term sent to Coder	System	08 Feb 2021 20:18:58
User entered 'other arthritis, back'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '15 Feb 2020'	Angela Snyder (b) (4)	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Angela Snyder (b) (4)	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Angela Snyder (b) (4)	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'Feb 2020'	System	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '2020'	System	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	08 Feb 2021 20:18:37

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 20:20:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 20:20:35
Data point term sent to Coder	System	08 Feb 2021 20:19:58
User entered 'coronary artery disease'	Angela Snyder (b) (4)	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '15 Jul 2002'	Angela Snyder (b) (4)	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Angela Snyder (b) (4)	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Angela Snyder (b) (4)	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'Jul 2002'	System	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '2002'	System	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 23:00:46

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered empty.	System	08 Feb 2021 20:19:14

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '27 Aug 2020'	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '11:50'	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '27 Aug 2020 11:50'	System	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '169.4' cm	(b) (4)	
	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57
DataPoint set to visible.	(b) (4)	
	System	28 Aug 2020 18:49:34

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '75.8' kg	(b) (4)	
	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57
DataPoint set to visible.	(b) (4)	
	System	28 Aug 2020 18:49:34

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered '26.41450'	System	28 Aug 2020 18:54:57
DataPoint set to visible.	System	28 Aug 2020 18:49:34

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'kg/m2'	System	28 Aug 2020 18:54:57
DataPoint set to visible.	System	28 Aug 2020 18:49:34

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '97.7' F	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'INFRARED THERMOMETER'	(b) (4)	
reason for change: Data Entry Error	Brenda Miller (b) (4)	23 Sep 2020 22:59:42
User entered 'temporal'	(b) (4)	
	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57
	(b) (4)	

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '50'	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'bpm'	System	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16'	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'breaths/min'	System	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '117'	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'mmHg'	System	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '79'	Sarah Trentman (b) (4)	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User entered 'mmHg'	System	28 Aug 2020 18:54:57

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53

US3662023

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53

US3662023

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	28 Aug 2020 18:55:41

US3662023

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:31:40
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 14:40:42
User entered '27 Aug 2020'	Sarah Trentman (b) (4) (b) (4)	28 Aug 2020 18:55:41

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
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	28 Aug 2020 18:58:47
User entered 'No (N)' reason for change: Data Entry Error	System	28 Aug 2020 18:58:47
User opened query 'Data is required. Please complete.' (Site from System).	Sarah Trentman (b) (4)	28 Aug 2020 18:58:47
User entered empty.	(b) (4)	
	System	28 Aug 2020 18:57:12
	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12
	(b) (4)	

US3662023

Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

[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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Sarah Trentman (b) (4)	28 Aug 2020 18:58:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

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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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'I'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

[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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

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)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '0'	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	28 Aug 2020 18:57:12

US3662023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	16 Sep 2020 14:40:42

US3662023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16 Sep 2020'	(b) (4) Sarah Trentman (b) (4)	16 Sep 2020 14:40:42

US3662023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Clinic (Clinic)'	Sarah Trentman (b) (4)	16 Sep 2020 14:40:42

US3662023

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'VISIT1'	System	16 Sep 2020 14:40:42

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 14:44:34

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '190924'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 14:44:34

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 14:44:34

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

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)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	16 Sep 2020 14:46:42

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

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)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	16 Sep 2020 14:46:42

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	16 Sep 2020 14:46:42

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	16 Sep 2020 14:46:42

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Sarah Trentman (b) (4)	16 Sep 2020 14:46:42

US3662023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 23:00:09
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:47:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:15:31

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '75.8' kg	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '75.8' kg	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16 Sep 2020'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '10:50'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '16 Sep 2020 10:50'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '97.8' F	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '53'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'bpm'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'breaths/min'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '114'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '68'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '75.8' kg	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16 Sep 2020'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '11:50'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '16 Sep 2020 11:50'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '97.7' F	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '52'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'bpm'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '14'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'breaths/min'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '117'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '71'	Brenda Miller (b) (4)	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	25 Sep 2020 16:02:14

US3662023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:03:57

US3662023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16 Sep 2020'	Brenda Miller (b) (4)	25 Sep 2020 16:03:57

US3662023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	16 Sep 2020 15:22:34
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	16 Sep 2020 15:22:34
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	16 Sep 2020 15:22:03
User entered 'Yes (Y)'	Sarah Trentman (b) (4)	16 Sep 2020 15:22:03

US3662023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	16 Sep 2020 15:22:03

US3662023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

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)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Sarah Trentman (b) (4)	16 Sep 2020 15:22:03

US3662023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 15:22:03

US3662023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Sarah Trentman (b) (4)	16 Sep 2020 15:22:34
User entered empty.	(b) (4)	
	Sarah Trentman (b) (4)	16 Sep 2020 15:22:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '11:19' reason for change: Data Entry Error	(b) (4)	
	Sarah Trentman (b) (4)	16 Sep 2020 15:22:34
User entered empty.	(b) (4)	
	Sarah Trentman (b) (4)	16 Sep 2020 15:22:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '16 Sep 2020 11:19'	System	16 Sep 2020 15:22:34
User entered empty.	System	16 Sep 2020 15:22:03

US3662023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4)	
	Sarah Trentman (b) (4)	16 Sep 2020 15:22:34
User entered empty.	(b) (4)	
	Sarah Trentman (b) (4)	16 Sep 2020 15:22:03
	(b) (4)	

US3662023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'ONCE'	System	16 Sep 2020 15:22:03

US3662023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 15:22:03

US3662023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:04:25

US3662023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16 Sep 2020'	Brenda Miller (b) (4)	25 Sep 2020 16:04:25

US3662023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '10:47'	Brenda Miller (b) (4)	25 Sep 2020 16:04:25

US3662023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '16 Sep 2020 10:47'	System	25 Sep 2020 16:04:25

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:00:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16 Sep 2020'	Brenda Miller (b) (4)	25 Sep 2020 16:04:54

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:04:54

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:04:54

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '10:55'	Brenda Miller (b) (4)	25 Sep 2020 16:04:54

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '16 Sep 2020 10:55'	System	25 Sep 2020 16:04:54

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:04:54

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Brenda Miller (b) (4)	25 Sep 2020 16:04:54

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:04:54

US3662023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered empty.	System	25 Sep 2020 16:04:54

US3662023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:05:01

US3662023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'I'	System	25 Sep 2020 16:05:01

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:53:27', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d1c05ec-089b-42f2-8baa-9c0e312fb38b'	System	16 Sep 2020 15:53:59
User entered 'Yes (Y)'	System	16 Sep 2020 15:53:59

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:53:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d1c05ec-089b-42f2-8baa-9c0e312fb38b'	System	16 Sep 2020 15:53:59
User entered '97.7'	System	16 Sep 2020 15:53:59

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:53:48', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d1c05ec-089b-42f2-8baa-9c0e312fb38b'	System	16 Sep 2020 15:53:59
User entered 'No (N)'	System	16 Sep 2020 15:53:59

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:53:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d1c05ec-089b-42f2-8baa-9c0e312fb38b'	System	16 Sep 2020 15:53:59
User entered '16 Sep 2020 11:53'	System	16 Sep 2020 15:53:59

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 11:39'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 14:09'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:57:02', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e597e054-1a75-4439-a0ba-59d36ecc070d'	System	17 Sep 2020 10:57:32
User entered 'Yes (Y)'	System	17 Sep 2020 10:57:32

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:57:12', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e597e054-1a75-4439-a0ba-59d36ecc070d' User entered '97.3'	System	17 Sep 2020 10:57:32
	System	17 Sep 2020 10:57:32

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:57:18', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e597e054-1a75-4439-a0ba-59d36ecc070d'	System	17 Sep 2020 10:57:32
User entered 'No (N)'	System	17 Sep 2020 10:57:32

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:57:25', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e597e054-1a75-4439-a0ba-59d36ecc070d'	System	17 Sep 2020 10:57:32
User entered '17 Sep 2020 06:57'	System	17 Sep 2020 10:57:32

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 15:04'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 2'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:13:34', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '71bb8635-1390-4449-81e3-61a4e4cf5ad7'	System	18 Sep 2020 12:13:57
User entered 'Yes (Y)'	System	18 Sep 2020 12:13:57

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:13:41', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '71bb8635-1390-4449-81e3-61a4e4cf5ad7'	System	18 Sep 2020 12:13:57
User entered '97.7'	System	18 Sep 2020 12:13:57

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:13:47', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '71bb8635-1390-4449-81e3-61a4e4cf5ad7'	System	18 Sep 2020 12:13:57
User entered 'No (N)'	System	18 Sep 2020 12:13:57

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:13:54', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '71bb8635-1390-4449-81e3-61a4e4cf5ad7'	System	18 Sep 2020 12:13:57
User entered '18 Sep 2020 08:13'	System	18 Sep 2020 12:13:57

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 3'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:13:54', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'ad140234-edcb-4dbc-abf6-06427fa167e9'	System	18 Sep 2020 16:14:32
User entered 'Yes (Y)'	System	18 Sep 2020 16:14:32

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:14:16', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'ad140234-edcb-4dbc-abf6-06427fa167e9'	System	18 Sep 2020 16:14:32
User entered '96.8'	System	18 Sep 2020 16:14:32

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:14:20', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'ad140234-edcb-4dbc-abf6-06427fa167e9'	System	18 Sep 2020 16:14:32
User entered 'No (N)'	System	18 Sep 2020 16:14:32

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:14:28', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'ad140234-edcb-4dbc-abf6-06427fa167e9'	System	18 Sep 2020 16:14:32
User entered '18 Sep 2020 12:14'	System	18 Sep 2020 16:14:32

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 4'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:12:46', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '31cbd5e0-f959-4cd5-99d6-04a72244629c'	System	19 Sep 2020 20:13:08
User entered 'Yes (Y)'	System	19 Sep 2020 20:13:08

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:12:53', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '31cbd5e0-f959-4cd5-99d6-04a72244629c' User entered '97.7'	System	19 Sep 2020 20:13:08
	System	19 Sep 2020 20:13:08

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:12:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '31cbd5e0-f959-4cd5-99d6-04a72244629c'	System	19 Sep 2020 20:13:08
User entered 'No (N)'	System	19 Sep 2020 20:13:08

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:13:03', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '31cbd5e0-f959-4cd5-99d6-04a72244629c'	System	19 Sep 2020 20:13:08
User entered '19 Sep 2020 16:13'	System	19 Sep 2020 20:13:08

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 5'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:47:14', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'b8583832-d13b-45aa-bec5-991ff937d80a'	System	21 Sep 2020 12:47:39
User entered 'Yes (Y)'	System	21 Sep 2020 12:47:39

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:47:21', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'b8583832-d13b-45aa-bec5-991ff937d80a'	System	21 Sep 2020 12:47:39
User entered '97.3'	System	21 Sep 2020 12:47:39

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:47:27', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'b8583832-d13b-45aa-bec5-991ff937d80a'	System	21 Sep 2020 12:47:39
User entered 'No (N)'	System	21 Sep 2020 12:47:39

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:47:33', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'b8583832-d13b-45aa-bec5-991ff937d80a'	System	21 Sep 2020 12:47:39
User entered '21 Sep 2020 08:47'	System	21 Sep 2020 12:47:39

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 6'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:25:23', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e46d0768-bc56-4c1e-8ee6-f03e09aa54b1'	System	21 Sep 2020 17:25:48
User entered 'Yes (Y)'	System	21 Sep 2020 17:25:48

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:25:30', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e46d0768-bc56-4c1e-8ee6-f03e09aa54b1' User entered '97.1'	System	21 Sep 2020 17:25:48
	System	21 Sep 2020 17:25:48

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:25:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e46d0768-bc56-4c1e-8ee6-f03e09aa54b1'	System	21 Sep 2020 17:25:48
User entered 'No (N)'	System	21 Sep 2020 17:25:48

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:25:40', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e46d0768-bc56-4c1e-8ee6-f03e09aa54b1'	System	21 Sep 2020 17:25:48
User entered '21 Sep 2020 13:25'	System	21 Sep 2020 17:25:48

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 7'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:10:33', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '51d24ae3-3cbb-4f1b-968c-e340604627e4'	System	22 Sep 2020 17:10:57
User entered 'Yes (Y)'	System	22 Sep 2020 17:10:57

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:10:39', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '51d24ae3-3cbb-4f1b-968c-e340604627e4'	System	22 Sep 2020 17:10:57
User entered '98.3'	System	22 Sep 2020 17:10:57

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:10:42', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '51d24ae3-3cbb-4f1b-968c-e340604627e4'	System	22 Sep 2020 17:10:57
User entered 'No (N)'	System	22 Sep 2020 17:10:57

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:10:52', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '51d24ae3-3cbb-4f1b-968c-e340604627e4'	System	22 Sep 2020 17:10:57
User entered '22 Sep 2020 13:10'	System	22 Sep 2020 17:10:57

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:54:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4f127281-3dee-4d3b-990d-fc72c0820ced'	System	16 Sep 2020 15:55:23
User entered 'None (1)'	System	16 Sep 2020 15:55:23

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:54:34', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4f127281-3dee-4d3b-990d-fc72c0820ced'	System	16 Sep 2020 15:55:23
User entered 'No (N)'	System	16 Sep 2020 15:55:23

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:54:39', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4f127281-3dee-4d3b-990d-fc72c0820ced'	System	16 Sep 2020 15:55:23
User entered 'No (N)'	System	16 Sep 2020 15:55:23

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:54:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4f127281-3dee-4d3b-990d-fc72c0820ced'	System	16 Sep 2020 15:55:23
User entered 'None (1)'	System	16 Sep 2020 15:55:23

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:06', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4f127281-3dee-4d3b-990d-fc72c0820ced'	System	16 Sep 2020 15:55:23
User entered '16 Sep 2020 11:55'	System	16 Sep 2020 15:55:23

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 11:39'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 14:09'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:57:36', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '67b4158f-d807-442f-ade9-9fec5b8578cc'	System	17 Sep 2020 10:58:28
User entered 'None (1)'	System	17 Sep 2020 10:58:28

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:57:51', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '67b4158f-d807-442f-ade9-9fec5b8578cc'	System	17 Sep 2020 10:58:28
User entered 'No (N)'	System	17 Sep 2020 10:58:28

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:57:55', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '67b4158f-d807-442f-ade9-9fec5b8578cc'	System	17 Sep 2020 10:58:28
User entered 'No (N)'	System	17 Sep 2020 10:58:28

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:13', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '67b4158f-d807-442f-ade9-9fec5b8578cc'	System	17 Sep 2020 10:58:28
User entered 'None (1)'	System	17 Sep 2020 10:58:28

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:25', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '67b4158f-d807-442f-ade9-9fec5b8578cc'	System	17 Sep 2020 10:58:28
User entered '17 Sep 2020 06:58'	System	17 Sep 2020 10:58:28

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 15:04'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 2'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:14:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9220f51b-5d50-4b45-80df-410ee9308d2e'	System	18 Sep 2020 12:14:45
User entered 'None (1)'	System	18 Sep 2020 12:14:45

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:14:13', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9220f51b-5d50-4b45-80df-410ee9308d2e'	System	18 Sep 2020 12:14:45
User entered 'No (N)'	System	18 Sep 2020 12:14:45

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:14:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9220f51b-5d50-4b45-80df-410ee9308d2e'	System	18 Sep 2020 12:14:45
User entered 'No (N)'	System	18 Sep 2020 12:14:45

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:14:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9220f51b-5d50-4b45-80df-410ee9308d2e'	System	18 Sep 2020 12:14:45
User entered 'None (1)'	System	18 Sep 2020 12:14:45

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:14:41', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9220f51b-5d50-4b45-80df-410ee9308d2e'	System	18 Sep 2020 12:14:45
User entered '18 Sep 2020 08:14'	System	18 Sep 2020 12:14:45

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 3'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:14:50', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4e38a72d-f8d3-47d2-bc70-38fc2cf296f8'	System	18 Sep 2020 16:15:41
User entered 'None (1)'	System	18 Sep 2020 16:15:41

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4e38a72d-f8d3-47d2-bc70-38fc2cf296f8'	System	18 Sep 2020 16:15:41
User entered 'No (N)'	System	18 Sep 2020 16:15:41

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4e38a72d-f8d3-47d2-bc70-38fc2cf296f8'	System	18 Sep 2020 16:15:41
User entered 'No (N)'	System	18 Sep 2020 16:15:41

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:20', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4e38a72d-f8d3-47d2-bc70-38fc2cf296f8'	System	18 Sep 2020 16:15:41
User entered 'None (1)'	System	18 Sep 2020 16:15:41

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:37', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4e38a72d-f8d3-47d2-bc70-38fc2cf296f8'	System	18 Sep 2020 16:15:41
User entered '18 Sep 2020 12:15'	System	18 Sep 2020 16:15:41

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 4'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:13:10', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2150c2f8-c86f-4051-9f60-8edfdb8ae9b'	System	19 Sep 2020 20:13:51
User entered 'None (1)'	System	19 Sep 2020 20:13:51

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:13:28', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2150c2f8-c86f-4051-9f60-8edfdb8ae9b'	System	19 Sep 2020 20:13:51
User entered 'No (N)'	System	19 Sep 2020 20:13:51

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:13:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2150c2f8-c86f-4051-9f60-8edfdb8ae9b'	System	19 Sep 2020 20:13:51
User entered 'No (N)'	System	19 Sep 2020 20:13:51

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:13:39', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2150c2f8-c86f-4051-9f60-8edfdb8ae9b'	System	19 Sep 2020 20:13:51
User entered 'None (1)'	System	19 Sep 2020 20:13:51

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:13:49', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2150c2f8-c86f-4051-9f60-8edfdb8ae9b'	System	19 Sep 2020 20:13:51
User entered '19 Sep 2020 16:13'	System	19 Sep 2020 20:13:51

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 5'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:47:43', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'cb2a30cc-fce4-495c-a5fe-dc3460410277'	System	21 Sep 2020 12:48:05
User entered 'None (1)'	System	21 Sep 2020 12:48:05

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:47:46', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'cb2a30cc-fce4-495c-a5fe-dc3460410277'	System	21 Sep 2020 12:48:05
User entered 'No (N)'	System	21 Sep 2020 12:48:05

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:47:49', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'cb2a30cc-fce4-495c-a5fe-dc3460410277'	System	21 Sep 2020 12:48:05
User entered 'No (N)'	System	21 Sep 2020 12:48:05

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:47:52', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'cb2a30cc-fce4-495c-a5fe-dc3460410277'	System	21 Sep 2020 12:48:05
User entered 'None (1)'	System	21 Sep 2020 12:48:05

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'cb2a30cc-fce4-495c-a5fe-dc3460410277'	System	21 Sep 2020 12:48:05
User entered '21 Sep 2020 08:48'	System	21 Sep 2020 12:48:05

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 6'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:25:52', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '6c845e6e-bad5-4c57-aac8-205da3184d53'	System	21 Sep 2020 17:26:19
User entered 'None (1)'	System	21 Sep 2020 17:26:19

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:25:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '6c845e6e-bad5-4c57-aac8-205da3184d53'	System	21 Sep 2020 17:26:19
User entered 'No (N)'	System	21 Sep 2020 17:26:19

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:25:59', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '6c845e6e-bad5-4c57-aac8-205da3184d53'	System	21 Sep 2020 17:26:19
User entered 'No (N)'	System	21 Sep 2020 17:26:19

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:03', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '6c845e6e-bad5-4c57-aac8-205da3184d53'	System	21 Sep 2020 17:26:19
User entered 'None (1)'	System	21 Sep 2020 17:26:19

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:13', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '6c845e6e-bad5-4c57-aac8-205da3184d53'	System	21 Sep 2020 17:26:19
User entered '21 Sep 2020 13:26'	System	21 Sep 2020 17:26:19

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 7'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:12', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c11a1a6b-73b2-4964-bfd6-6d6c386b7c89'	System	22 Sep 2020 17:11:37
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:15', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c11a1a6b-73b2-4964-bfd6-6d6c386b7c89'	System	22 Sep 2020 17:11:37
User entered 'No (N)'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:18', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c11a1a6b-73b2-4964-bfd6-6d6c386b7c89'	System	22 Sep 2020 17:11:37
User entered 'No (N)'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:22', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c11a1a6b-73b2-4964-bfd6-6d6c386b7c89'	System	22 Sep 2020 17:11:37
User entered 'None (1)'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c11a1a6b-73b2-4964-bfd6-6d6c386b7c89'	System	22 Sep 2020 17:11:37
User entered '22 Sep 2020 13:11'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:15', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '5baf6bb2-e638-4c43-a48a-0f3360b91439'	System	16 Sep 2020 15:56:03
User entered 'None (0)'	System	16 Sep 2020 15:56:03

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:18', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '5baf6bb2-e638-4c43-a48a-0f3360b91439' User entered 'None (0)'	System	16 Sep 2020 15:56:03
	System	16 Sep 2020 15:56:03

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:22', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '5baf6bb2-e638-4c43-a48a-0f3360b91439'	System	16 Sep 2020 15:56:03
User entered 'None (0)'	System	16 Sep 2020 15:56:03

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:26', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '5baf6bb2-e638-4c43-a48a-0f3360b91439'	System	16 Sep 2020 15:56:03
User entered 'None (0)'	System	16 Sep 2020 15:56:03

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:30', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '5baf6bb2-e638-4c43-a48a-0f3360b91439'	System	16 Sep 2020 15:56:03
User entered 'None (0)'	System	16 Sep 2020 15:56:03

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:33', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '5baf6bb2-e638-4c43-a48a-0f3360b91439'	System	16 Sep 2020 15:56:03
User entered 'None (0)'	System	16 Sep 2020 15:56:03

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:46', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '5baf6bb2-e638-4c43-a48a-0f3360b91439'	System	16 Sep 2020 15:56:03
User entered 'No (N)'	System	16 Sep 2020 15:56:03

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-16T11:55:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '5baf6bb2-e638-4c43-a48a-0f3360b91439'	System	16 Sep 2020 15:56:03
User entered '16 Sep 2020 11:55'	System	16 Sep 2020 15:56:03

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 11:39'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 14:09'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4a52dfaf-5f2a-4842-b584-2aecc4adfd8'	System	17 Sep 2020 10:59:12
User entered 'None (0)'	System	17 Sep 2020 10:59:12

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4a52dfaf-5f2a-4842-b584-2aecc4adfd8'	System	17 Sep 2020 10:59:12
User entered 'None (0)'	System	17 Sep 2020 10:59:12

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:38', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4a52dfaf-5f2a-4842-b584-2aecc4adfa8'	System	17 Sep 2020 10:59:12
User entered 'None (0)'	System	17 Sep 2020 10:59:12

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:42', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4a52dfaf-5f2a-4842-b584-2aecc4adfd8'	System	17 Sep 2020 10:59:12
User entered 'None (0)'	System	17 Sep 2020 10:59:12

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:46', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4a52dfaf-5f2a-4842-b584-2aecc4adfd8'	System	17 Sep 2020 10:59:12
User entered 'None (0)'	System	17 Sep 2020 10:59:12

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:48', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4a52dfaf-5f2a-4842-b584-2aecc4adfd8'	System	17 Sep 2020 10:59:12
User entered 'None (0)'	System	17 Sep 2020 10:59:12

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:58:53', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4a52dfaf-5f2a-4842-b584-2aecc4adfd8'	System	17 Sep 2020 10:59:12
User entered 'No (N)'	System	17 Sep 2020 10:59:12

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-17T06:59:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4a52dfaf-5f2a-4842-b584-2aecc4adfd8'	System	17 Sep 2020 10:59:12
User entered '17 Sep 2020 06:59'	System	17 Sep 2020 10:59:12

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Sep 2020 15:04'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 2'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:14:48', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9bf53a67-f631-4a85-85eb-cfc4264bd7db'	System	18 Sep 2020 12:15:26
User entered 'None (0)'	System	18 Sep 2020 12:15:26

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:14:51', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9bf53a67-f631-4a85-85eb-cfc4264bd7db'	System	18 Sep 2020 12:15:26
User entered 'None (0)'	System	18 Sep 2020 12:15:26

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:14:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9bf53a67-f631-4a85-85eb-cfc4264bd7db'	System	18 Sep 2020 12:15:26
User entered 'None (0)'	System	18 Sep 2020 12:15:26

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:15:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9bf53a67-f631-4a85-85eb-cfc4264bd7db'	System	18 Sep 2020 12:15:26
User entered 'None (0)'	System	18 Sep 2020 12:15:26

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:15:03', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9bf53a67-f631-4a85-85eb-cfc4264bd7db'	System	18 Sep 2020 12:15:26
User entered 'None (0)'	System	18 Sep 2020 12:15:26

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:15:06', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9bf53a67-f631-4a85-85eb-cfc4264bd7db'	System	18 Sep 2020 12:15:26
User entered 'None (0)'	System	18 Sep 2020 12:15:26

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:15:11', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9bf53a67-f631-4a85-85eb-cfc4264bd7db'	System	18 Sep 2020 12:15:26
User entered 'No (N)'	System	18 Sep 2020 12:15:26

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T08:15:23', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9bf53a67-f631-4a85-85eb-cfc4264bd7db'	System	18 Sep 2020 12:15:26
User entered '18 Sep 2020 08:15'	System	18 Sep 2020 12:15:26

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 3'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:45', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e6005941-6d1a-4ffd-b100-8be58031a9b6'	System	18 Sep 2020 16:16:19
User entered 'None (0)'	System	18 Sep 2020 16:16:19

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:48', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e6005941-6d1a-4ffd-b100-8be58031a9b6'	System	18 Sep 2020 16:16:19
User entered 'None (0)'	System	18 Sep 2020 16:16:19

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:51', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e6005941-6d1a-4ffd-b100-8be58031a9b6'	System	18 Sep 2020 16:16:19
User entered 'None (0)'	System	18 Sep 2020 16:16:19

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:55', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e6005941-6d1a-4ffd-b100-8be58031a9b6'	System	18 Sep 2020 16:16:19
User entered 'None (0)'	System	18 Sep 2020 16:16:19

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:15:58', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e6005941-6d1a-4ffd-b100-8be58031a9b6'	System	18 Sep 2020 16:16:19
User entered 'None (0)'	System	18 Sep 2020 16:16:19

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:16:01', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e6005941-6d1a-4ffd-b100-8be58031a9b6'	System	18 Sep 2020 16:16:19
User entered 'None (0)'	System	18 Sep 2020 16:16:19

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:16:07', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e6005941-6d1a-4ffd-b100-8be58031a9b6'	System	18 Sep 2020 16:16:19
User entered 'No (N)'	System	18 Sep 2020 16:16:19

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-18T12:16:15', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e6005941-6d1a-4ffd-b100-8be58031a9b6'	System	18 Sep 2020 16:16:19
User entered '18 Sep 2020 12:16'	System	18 Sep 2020 16:16:19

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 4'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:13:53', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '11aab07b-134c-4d92-bb5c-4184a9f7facd'	System	19 Sep 2020 20:14:28
User entered 'None (0)'	System	19 Sep 2020 20:14:28

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:13:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '11aab07b-134c-4d92-bb5c-4184a9f7facd'	System	19 Sep 2020 20:14:28
User entered 'None (0)'	System	19 Sep 2020 20:14:28

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:14:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '11aab07b-134c-4d92-bb5c-4184a9f7facd'	System	19 Sep 2020 20:14:28
User entered 'None (0)'	System	19 Sep 2020 20:14:28

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:14:06', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '11aab07b-134c-4d92-bb5c-4184a9f7facd'	System	19 Sep 2020 20:14:28
User entered 'None (0)'	System	19 Sep 2020 20:14:28

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:14:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '11aab07b-134c-4d92-bb5c-4184a9f7facd'	System	19 Sep 2020 20:14:28
User entered 'None (0)'	System	19 Sep 2020 20:14:28

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:14:12', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '11aab07b-134c-4d92-bb5c-4184a9f7facd'	System	19 Sep 2020 20:14:28
User entered 'None (0)'	System	19 Sep 2020 20:14:28

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:14:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '11aab07b-134c-4d92-bb5c-4184a9f7facd'	System	19 Sep 2020 20:14:28
User entered 'No (N)'	System	19 Sep 2020 20:14:28

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-19T16:14:25', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '11aab07b-134c-4d92-bb5c-4184a9f7facd'	System	19 Sep 2020 20:14:28
User entered '19 Sep 2020 16:14'	System	19 Sep 2020 20:14:28

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 5'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:04', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '0516f56a-9525-4384-8eb7-761e139ac9cf'	System	21 Sep 2020 12:48:36
User entered 'None (0)'	System	21 Sep 2020 12:48:36

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:07', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '0516f56a-9525-4384-8eb7-761e139ac9cf'	System	21 Sep 2020 12:48:36
User entered 'None (0)'	System	21 Sep 2020 12:48:36

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:10', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '0516f56a-9525-4384-8eb7-761e139ac9cf'	System	21 Sep 2020 12:48:36
User entered 'None (0)'	System	21 Sep 2020 12:48:36

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:15', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '0516f56a-9525-4384-8eb7-761e139ac9cf'	System	21 Sep 2020 12:48:36
User entered 'None (0)'	System	21 Sep 2020 12:48:36

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:18', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '0516f56a-9525-4384-8eb7-761e139ac9cf'	System	21 Sep 2020 12:48:36
User entered 'None (0)'	System	21 Sep 2020 12:48:36

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:20', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '0516f56a-9525-4384-8eb7-761e139ac9cf'	System	21 Sep 2020 12:48:36
User entered 'None (0)'	System	21 Sep 2020 12:48:36

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:24', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '0516f56a-9525-4384-8eb7-761e139ac9cf'	System	21 Sep 2020 12:48:36
User entered 'No (N)'	System	21 Sep 2020 12:48:36

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T08:48:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '0516f56a-9525-4384-8eb7-761e139ac9cf'	System	21 Sep 2020 12:48:36
User entered '21 Sep 2020 08:48'	System	21 Sep 2020 12:48:36

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 6'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4750f7c0-3b67-4ae6-9614-1da926097875'	System	21 Sep 2020 17:27:13
User entered 'None (0)'	System	21 Sep 2020 17:27:13

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:29', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4750f7c0-3b67-4ae6-9614-1da926097875'	System	21 Sep 2020 17:27:13
User entered 'None (0)'	System	21 Sep 2020 17:27:13

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:32', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4750f7c0-3b67-4ae6-9614-1da926097875'	System	21 Sep 2020 17:27:13
User entered 'None (0)'	System	21 Sep 2020 17:27:13

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:37', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4750f7c0-3b67-4ae6-9614-1da926097875'	System	21 Sep 2020 17:27:13
User entered 'None (0)'	System	21 Sep 2020 17:27:13

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:47', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4750f7c0-3b67-4ae6-9614-1da926097875'	System	21 Sep 2020 17:27:13
User entered 'None (0)'	System	21 Sep 2020 17:27:13

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:50', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4750f7c0-3b67-4ae6-9614-1da926097875'	System	21 Sep 2020 17:27:13
User entered 'None (0)'	System	21 Sep 2020 17:27:13

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:26:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4750f7c0-3b67-4ae6-9614-1da926097875'	System	21 Sep 2020 17:27:13
User entered 'No (N)'	System	21 Sep 2020 17:27:13

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-21T13:27:07', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4750f7c0-3b67-4ae6-9614-1da926097875'	System	21 Sep 2020 17:27:13
User entered '21 Sep 2020 13:27'	System	21 Sep 2020 17:27:13

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 7'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:36', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4bbf9957-1651-41d2-8fea-a9341e634b43'	System	22 Sep 2020 17:12:09
User entered 'None (0)'	System	22 Sep 2020 17:12:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:39', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4bbf9957-1651-41d2-8fea-a9341e634b43'	System	22 Sep 2020 17:12:09
User entered 'None (0)'	System	22 Sep 2020 17:12:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:42', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4bbf9957-1651-41d2-8fea-a9341e634b43'	System	22 Sep 2020 17:12:09
User entered 'None (0)'	System	22 Sep 2020 17:12:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:45', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4bbf9957-1651-41d2-8fea-a9341e634b43'	System	22 Sep 2020 17:12:09
User entered 'None (0)'	System	22 Sep 2020 17:12:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:49', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4bbf9957-1651-41d2-8fea-a9341e634b43'	System	22 Sep 2020 17:12:09
User entered 'None (0)'	System	22 Sep 2020 17:12:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:51', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4bbf9957-1651-41d2-8fea-a9341e634b43'	System	22 Sep 2020 17:12:09
User entered 'None (0)'	System	22 Sep 2020 17:12:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:11:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4bbf9957-1651-41d2-8fea-a9341e634b43'	System	22 Sep 2020 17:12:09
User entered 'No (N)'	System	22 Sep 2020 17:12:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-22T13:12:05', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4bbf9957-1651-41d2-8fea-a9341e634b43'	System	22 Sep 2020 17:12:09
User entered '22 Sep 2020 13:12'	System	22 Sep 2020 17:12:09

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	22 Sep 2020 17:11:37
User entered 'Day 8'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-24T08:40:01', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '19824878-7f59-48bd-90ce-9fe82560fd36'	System	24 Sep 2020 12:40:12
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 12:40:12

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-24T08:40:06', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '19824878-7f59-48bd-90ce-9fe82560fd36'	System	24 Sep 2020 12:40:12
User entered '24 Sep 2020 08:40'	System	24 Sep 2020 12:40:12

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	22 Sep 2020 17:11:37
User entered 'Day 9'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-24T13:12:02', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'a3114247-ad1c-457d-bfca-bc4dd39b9233'	System	24 Sep 2020 17:12:11
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 17:12:11

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-24T13:12:08', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'a3114247-ad1c-457d-bfca-bc4dd39b9233'	System	24 Sep 2020 17:12:11
User entered '24 Sep 2020 13:12'	System	24 Sep 2020 17:12:11

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	24 Sep 2020 12:40:12
User entered 'Day 10'	System	24 Sep 2020 12:40:12

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-26T07:28:42', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '12ac7737-1ec5-48cb-904b-b184cddbbae8b'	System	26 Sep 2020 11:28:51
User entered 'None (1)'	System	26 Sep 2020 11:28:51

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-26T07:28:46', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '12ac7737-1ec5-48cb-904b-b184cddb8b'	System	26 Sep 2020 11:28:51
User entered '26 Sep 2020 07:28'	System	26 Sep 2020 11:28:51

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 12:40:12

US3662023

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 12:40:12

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	22 Sep 2020 17:11:37
User entered 'Day 8'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-24T08:40:30', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9639bd31-e740-481f-85c5-28a5296b5cf9'	System	24 Sep 2020 12:40:40
User entered 'No (N)'	System	24 Sep 2020 12:40:40

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-24T08:40:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9639bd31-e740-481f-85c5-28a5296b5cf9'	System	24 Sep 2020 12:40:40
User entered '24 Sep 2020 08:40'	System	24 Sep 2020 12:40:40

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	22 Sep 2020 17:11:37
User entered 'Day 9'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-24T13:12:15', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c88e714d-f425-4929-bcb5-910ff0b54f05'	System	24 Sep 2020 17:12:22
User entered 'No (N)'	System	24 Sep 2020 17:12:22

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-24T13:12:18', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c88e714d-f425-4929-bcb5-910ff0b54f05'	System	24 Sep 2020 17:12:22
User entered '24 Sep 2020 13:12'	System	24 Sep 2020 17:12:22

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:11:37

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	24 Sep 2020 12:40:12
User entered 'Day 10'	System	24 Sep 2020 12:40:12

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-26T07:28:54', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '06f2cdae-f31d-41d7-8624-e9a0ae77e2bb'	System	26 Sep 2020 11:29:02
User entered 'No (N)'	System	26 Sep 2020 11:29:02

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3030f78f4b6994af)', Time: '2020-09-26T07:28:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '06f2cdae-f31d-41d7-8624-e9a0ae77e2bb'	System	26 Sep 2020 11:29:02
User entered '26 Sep 2020 07:28'	System	26 Sep 2020 11:29:02

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 12:40:12

US3662023

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 12:40:12

US3662023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 17:05:19

US3662023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '24 Sep 2020'	Brenda Miller (b) (4)	25 Sep 2020 17:05:19

US3662023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	25 Sep 2020 17:05:19

US3662023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 17:05:19

US3662023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	01 Oct 2020 19:25:08

US3662023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'I'	System	01 Oct 2020 19:25:08

US3662023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	01 Oct 2020 19:26:21

US3662023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '01 Oct 2020'	Brenda Miller (b) (4)	01 Oct 2020 19:26:21

US3662023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	01 Oct 2020 19:26:21

US3662023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	01 Oct 2020 19:26:21

US3662023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	07 Oct 2020 15:54:30

US3662023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User entered 'I'	System	07 Oct 2020 15:54:30

US3662023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	07 Oct 2020 15:54:50

US3662023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '07 Oct 2020'	Brenda Miller (b) (4)	07 Oct 2020 15:54:50

US3662023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	07 Oct 2020 15:54:50

US3662023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	07 Oct 2020 15:54:50

US3662023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	MaKayla Bishop (b) (4)	14 Oct 2020 14:30:16

US3662023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:48
User entered 'I'	System	14 Oct 2020 14:30:16

US3662023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:31:09

US3662023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:31:09

US3662023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	15 Oct 2020 15:31:09

US3662023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'VISIT2'	System	15 Oct 2020 15:31:09

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '10:32'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '14 Oct 2020 10:32'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '97.7' F	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '55'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'bpm'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'breaths/min'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '123'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '73'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '11:50'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '14 Oct 2020 11:50'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '98.0' F	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '54'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'bpm'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'breaths/min'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '111'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '72'	Brenda Miller (b) (4)	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	15 Oct 2020 15:33:18

US3662023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:33:30

US3662023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:33:30

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

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)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	MaKayla Bishop (b) (4)	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'MRNA-1273 OR PLACEBO'	System	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '14 Oct 2020'	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '11:17'	(b) (4) MaKayla Bishop (b) (4)	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '14 Oct 2020 11:17'	System	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'ONCE'	System	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'INTRAMUSCULAR'	System	14 Oct 2020 15:20:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:34:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:34:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '10:55'	Brenda Miller (b) (4)	15 Oct 2020 15:34:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '14 Oct 2020 10:55'	System	15 Oct 2020 15:34:04

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:00:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '14 Oct 2020'	Brenda Miller (b) (4)	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '10:50'	Brenda Miller (b) (4)	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '14 Oct 2020 10:50'	System	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Brenda Miller (b) (4)	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered empty.	System	15 Oct 2020 15:34:27

US3662023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	15 Oct 2020 15:34:36

US3662023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'I'	System	15 Oct 2020 15:34:36

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:43:22', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd02612fb-cfd1-459a-bcbc-a54aa4cdde7e' User entered 'Yes (Y)'	System	14 Oct 2020 15:44:30
	System	14 Oct 2020 15:44:30

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:43:36', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd02612fb-cfd1-459a-bcbc-a54aa4cdde7e' User entered '98.0'	System	14 Oct 2020 15:44:30
	System	14 Oct 2020 15:44:30

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:43:53', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd02612fb-cfd1-459a-bcbc-a54aa4cdde7e' User entered 'No (N)'	System	14 Oct 2020 15:44:30
	System	14 Oct 2020 15:44:30

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:43:59', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd02612fb-cfd1-459a-bcbc-a54aa4cdde7e' User entered '14 Oct 2020 11:43'	System	14 Oct 2020 15:44:30
	System	14 Oct 2020 15:44:30

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 11:37'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 14:07'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:01', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'dab2a707-5e2d-4f78-a363-7ee0028893d3' User entered 'Yes (Y)'	System	15 Oct 2020 00:56:26
	System	15 Oct 2020 00:56:26

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'dab2a707-5e2d-4f78-a363-7ee0028893d3' User entered '97.7'	System	15 Oct 2020 00:56:26
	System	15 Oct 2020 00:56:26

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:13', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'dab2a707-5e2d-4f78-a363-7ee0028893d3'	System	15 Oct 2020 00:56:26
User entered 'No (N)'	System	15 Oct 2020 00:56:26

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:24', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'dab2a707-5e2d-4f78-a363-7ee0028893d3' User entered '14 Oct 2020 20:56'	System	15 Oct 2020 00:56:26
	System	15 Oct 2020 00:56:26

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 15:02'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 2'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:08:50', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1ce3a672-d737-4832-a6b5-f276c61820a4' User entered 'Yes (Y)'	System	15 Oct 2020 17:09:13
	System	15 Oct 2020 17:09:13

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:08:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1ce3a672-d737-4832-a6b5-f276c61820a4' User entered '97.3'	System	15 Oct 2020 17:09:13
	System	15 Oct 2020 17:09:13

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:02', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1ce3a672-d737-4832-a6b5-f276c61820a4' User entered 'No (N)'	System	15 Oct 2020 17:09:13
	System	15 Oct 2020 17:09:13

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1ce3a672-d737-4832-a6b5-f276c61820a4' User entered '15 Oct 2020 13:09'	System	15 Oct 2020 17:09:13
	System	15 Oct 2020 17:09:13

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 3'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:50:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2d9727fe-a4f6-4a8b-ba67-4d66ea3c4950' User entered 'Yes (Y)'	System	16 Oct 2020 18:50:47
	System	16 Oct 2020 18:50:47

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:50:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2d9727fe-a4f6-4a8b-ba67-4d66ea3c4950' User entered '97.6'	System	16 Oct 2020 18:50:47
	System	16 Oct 2020 18:50:47

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:50:38', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2d9727fe-a4f6-4a8b-ba67-4d66ea3c4950'	System	16 Oct 2020 18:50:47
User entered 'No (N)'	System	16 Oct 2020 18:50:47

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:50:42', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2d9727fe-a4f6-4a8b-ba67-4d66ea3c4950' User entered '16 Oct 2020 14:50'	System	16 Oct 2020 18:50:47
	System	16 Oct 2020 18:50:47

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 4'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:23', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '812139a4-1cda-4961-95c3-7d494a31b6cb' User entered 'Yes (Y)'	System	18 Oct 2020 12:20:36
	System	18 Oct 2020 12:20:36

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:27', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '812139a4-1cda-4961-95c3-7d494a31b6cb' User entered '97.3'	System	18 Oct 2020 12:20:36
	System	18 Oct 2020 12:20:36

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '812139a4-1cda-4961-95c3-7d494a31b6cb' User entered 'No (N)'	System	18 Oct 2020 12:20:36
	System	18 Oct 2020 12:20:36

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '812139a4-1cda-4961-95c3-7d494a31b6cb' User entered '18 Oct 2020 08:20'	System	18 Oct 2020 12:20:36
	System	18 Oct 2020 12:20:36

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 5'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:42:36', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4407c6ed-cec7-4c6c-9277-1710f3b1fce3' User entered 'Yes (Y)'	System	19 Oct 2020 11:43:22
	System	19 Oct 2020 11:43:22

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:42:50', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4407c6ed-cec7-4c6c-9277-1710f3b1fce3' User entered '97.4'	System	19 Oct 2020 11:43:22
	System	19 Oct 2020 11:43:22

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:42:54', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4407c6ed-cec7-4c6c-9277-1710f3b1fce3'	System	19 Oct 2020 11:43:22
User entered 'No (N)'	System	19 Oct 2020 11:43:22

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:21', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4407c6ed-cec7-4c6c-9277-1710f3b1fce3' User entered '19 Oct 2020 07:43'	System	19 Oct 2020 11:43:22
	System	19 Oct 2020 11:43:22

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 6'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:04', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9dc02f01-a6fe-4b1c-ba13-ca03a0592c91' User entered 'Yes (Y)'	System	19 Oct 2020 17:03:23
	System	19 Oct 2020 17:03:23

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:11', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9dc02f01-a6fe-4b1c-ba13-ca03a0592c91' User entered '97.7'	System	19 Oct 2020 17:03:23
	System	19 Oct 2020 17:03:23

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:15', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9dc02f01-a6fe-4b1c-ba13-ca03a0592c91'	System	19 Oct 2020 17:03:23
User entered 'No (N)'	System	19 Oct 2020 17:03:23

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:19', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9dc02f01-a6fe-4b1c-ba13-ca03a0592c91' User entered '19 Oct 2020 13:03'	System	19 Oct 2020 17:03:23
	System	19 Oct 2020 17:03:23

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 7'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:13', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'af278fff-03c6-42d1-8f48-46db1ee3c29b' User entered 'Yes (Y)'	System	20 Oct 2020 16:03:19
	System	20 Oct 2020 16:03:19

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:21', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'af278fff-03c6-42d1-8f48-46db1ee3c29b' User entered '97.1'	System	20 Oct 2020 16:03:19
	System	20 Oct 2020 16:03:19

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:25', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'af278fff-03c6-42d1-8f48-46db1ee3c29b'	System	20 Oct 2020 16:03:19
User entered 'No (N)'	System	20 Oct 2020 16:03:19

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:28', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'af278fff-03c6-42d1-8f48-46db1ee3c29b' User entered '20 Oct 2020 12:02'	System	20 Oct 2020 16:03:19
	System	20 Oct 2020 16:03:19

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:05', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '3c040963-dedf-4652-b8a4-466c4d9de15c' User entered 'None (1)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:08', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '3c040963-dedf-4652-b8a4-466c4d9de15c' User entered 'No (N)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:12', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '3c040963-dedf-4652-b8a4-466c4d9de15c' User entered 'No (N)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:15', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '3c040963-dedf-4652-b8a4-466c4d9de15c' User entered 'None (1)'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:23', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '3c040963-dedf-4652-b8a4-466c4d9de15c' User entered '14 Oct 2020 11:44'	System	14 Oct 2020 15:44:40
	System	14 Oct 2020 15:44:40

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 11:37'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 14:07'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bde223c0-1ba7-4184-86e1-086e672ad9d2'	System	15 Oct 2020 00:56:59
User entered 'None (1)'	System	15 Oct 2020 00:56:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bde223c0-1ba7-4184-86e1-086e672ad9d2' User entered 'No (N)'	System	15 Oct 2020 00:56:59
	System	15 Oct 2020 00:56:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:39', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bde223c0-1ba7-4184-86e1-086e672ad9d2' User entered 'No (N)'	System	15 Oct 2020 00:56:59
	System	15 Oct 2020 00:56:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:43', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bde223c0-1ba7-4184-86e1-086e672ad9d2'	System	15 Oct 2020 00:56:59
User entered 'None (1)'	System	15 Oct 2020 00:56:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:56:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bde223c0-1ba7-4184-86e1-086e672ad9d2' User entered '14 Oct 2020 20:56'	System	15 Oct 2020 00:56:59
	System	15 Oct 2020 00:56:59

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 15:02'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 2'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:36', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'a6b7746b-8a63-4c58-9056-dfb20e43f167'	System	15 Oct 2020 17:09:52
User entered 'None (1)'	System	15 Oct 2020 17:09:52

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:19', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'a6b7746b-8a63-4c58-9056-dfb20e43f167'	System	15 Oct 2020 17:09:52
User entered 'No (N)'	System	15 Oct 2020 17:09:52

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:25', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'a6b7746b-8a63-4c58-9056-dfb20e43f167' User entered 'No (N)'	System	15 Oct 2020 17:09:52
	System	15 Oct 2020 17:09:52

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:29', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'a6b7746b-8a63-4c58-9056-dfb20e43f167'	System	15 Oct 2020 17:09:52
User entered 'None (1)'	System	15 Oct 2020 17:09:52

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:46', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'a6b7746b-8a63-4c58-9056-dfb20e43f167' User entered '15 Oct 2020 13:09'	System	15 Oct 2020 17:09:52
	System	15 Oct 2020 17:09:52

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 3'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:50:47', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '92baabfc-bf47-46d2-8ee3-5899e8dbdedc' User entered 'None (1)'	System	16 Oct 2020 18:51:10
	System	16 Oct 2020 18:51:10

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:50:50', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '92baabfc-bf47-46d2-8ee3-5899e8dbdedc' User entered 'No (N)'	System	16 Oct 2020 18:51:10
	System	16 Oct 2020 18:51:10

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:50:53', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '92baabfc-bf47-46d2-8ee3-5899e8dbdedc' User entered 'No (N)'	System	16 Oct 2020 18:51:10
	System	16 Oct 2020 18:51:10

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:50:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '92baabfc-bf47-46d2-8ee3-5899e8dbdedc' User entered 'None (1)'	System	16 Oct 2020 18:51:10
	System	16 Oct 2020 18:51:10

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:05', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '92baabfc-bf47-46d2-8ee3-5899e8dbdedc' User entered '16 Oct 2020 14:51'	System	16 Oct 2020 18:51:10
	System	16 Oct 2020 18:51:10

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 4'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:42', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd1e05f54-8986-41b7-88d9-c522ec395b20'	System	18 Oct 2020 12:20:58
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 12:20:58

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:46', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd1e05f54-8986-41b7-88d9-c522ec395b20' User entered 'No (N)'	System	18 Oct 2020 12:20:58
	System	18 Oct 2020 12:20:58

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:49', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd1e05f54-8986-41b7-88d9-c522ec395b20' User entered 'No (N)'	System	18 Oct 2020 12:20:58
	System	18 Oct 2020 12:20:58

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:52', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd1e05f54-8986-41b7-88d9-c522ec395b20' User entered 'None (1)'	System	18 Oct 2020 12:20:58
	System	18 Oct 2020 12:20:58

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:20:55', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd1e05f54-8986-41b7-88d9-c522ec395b20' User entered '18 Oct 2020 08:20'	System	18 Oct 2020 12:20:58
	System	18 Oct 2020 12:20:58

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 5'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:25', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7a1e62f8-0538-408e-88ae-7692c51ea133'	System	19 Oct 2020 11:43:41
User entered 'None (1)'	System	19 Oct 2020 11:43:41

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:29', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7a1e62f8-0538-408e-88ae-7692c51ea133' User entered 'No (N)'	System	19 Oct 2020 11:43:41
	System	19 Oct 2020 11:43:41

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:32', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7a1e62f8-0538-408e-88ae-7692c51ea133'	System	19 Oct 2020 11:43:41
User entered 'No (N)'	System	19 Oct 2020 11:43:41

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:34', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7a1e62f8-0538-408e-88ae-7692c51ea133'	System	19 Oct 2020 11:43:41
User entered 'None (1)'	System	19 Oct 2020 11:43:41

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:38', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7a1e62f8-0538-408e-88ae-7692c51ea133' User entered '19 Oct 2020 07:43'	System	19 Oct 2020 11:43:41
	System	19 Oct 2020 11:43:41

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 6'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:24', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bbclcbcb-9ccb-4f4d-b6a5-c47855447b26'	System	19 Oct 2020 17:03:45
User entered 'None (1)'	System	19 Oct 2020 17:03:45

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:27', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bbc1ebcb-9ccb-4f4d-b6a5-c47855447b26' User entered 'No (N)'	System	19 Oct 2020 17:03:45
	System	19 Oct 2020 17:03:45

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bbc1ebcb-9ccb-4f4d-b6a5-c47855447b26' User entered 'No (N)'	System	19 Oct 2020 17:03:45
	System	19 Oct 2020 17:03:45

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:34', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bbc1ebcb-9ccb-4f4d-b6a5-c47855447b26' User entered 'None (1)'	System	19 Oct 2020 17:03:45
	System	19 Oct 2020 17:03:45

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:43', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bbc1ebcb-9ccb-4f4d-b6a5-c47855447b26' User entered '19 Oct 2020 13:03'	System	19 Oct 2020 17:03:45
	System	19 Oct 2020 17:03:45

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 7'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:37', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e602b9fa-cc8d-4637-af0f-d9f923199fc7'	System	20 Oct 2020 16:03:48
User entered 'None (1)'	System	20 Oct 2020 16:03:48

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:41', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e602b9fa-cc8d-4637-af0f-d9f923199fc7'	System	20 Oct 2020 16:03:48
User entered 'No (N)'	System	20 Oct 2020 16:03:48

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:45', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e602b9fa-cc8d-4637-af0f-d9f923199fc7'	System	20 Oct 2020 16:03:48
User entered 'No (N)'	System	20 Oct 2020 16:03:48

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:49', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e602b9fa-cc8d-4637-af0f-d9f923199fc7'	System	20 Oct 2020 16:03:48
User entered 'None (1)'	System	20 Oct 2020 16:03:48

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:52', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e602b9fa-cc8d-4637-af0f-d9f923199fc7' User entered '20 Oct 2020 12:02'	System	20 Oct 2020 16:03:48
	System	20 Oct 2020 16:03:48

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:28', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '28783b03-9924-4985-b14e-e5529f15a10b' User entered 'None (0)'	System	14 Oct 2020 15:45:04
	System	14 Oct 2020 15:45:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '28783b03-9924-4985-b14e-e5529f15a10b' User entered 'None (0)'	System	14 Oct 2020 15:45:04
	System	14 Oct 2020 15:45:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '28783b03-9924-4985-b14e-e5529f15a10b' User entered 'None (0)'	System	14 Oct 2020 15:45:04
	System	14 Oct 2020 15:45:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:38', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '28783b03-9924-4985-b14e-e5529f15a10b' User entered 'None (0)'	System	14 Oct 2020 15:45:04
	System	14 Oct 2020 15:45:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:41', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '28783b03-9924-4985-b14e-e5529f15a10b' User entered 'None (0)'	System	14 Oct 2020 15:45:04
	System	14 Oct 2020 15:45:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:44', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '28783b03-9924-4985-b14e-e5529f15a10b' User entered 'None (0)'	System	14 Oct 2020 15:45:04
	System	14 Oct 2020 15:45:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:52', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '28783b03-9924-4985-b14e-e5529f15a10b' User entered 'No (N)'	System	14 Oct 2020 15:45:04
	System	14 Oct 2020 15:45:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T11:44:59', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '28783b03-9924-4985-b14e-e5529f15a10b' User entered '14 Oct 2020 11:44'	System	14 Oct 2020 15:45:04
	System	14 Oct 2020 15:45:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 11:37'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 14:07'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 1, after vaccination (at home)'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:57:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d6fc662-6706-47ee-a3b2-d931a9124fe8' User entered 'None (0)'	System	15 Oct 2020 00:57:55
	System	15 Oct 2020 00:57:55

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:57:07', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d6fc662-6706-47ee-a3b2-d931a9124fe8' User entered 'None (0)'	System	15 Oct 2020 00:57:55
	System	15 Oct 2020 00:57:55

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:57:13', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d6fc662-6706-47ee-a3b2-d931a9124fe8' User entered 'None (0)'	System	15 Oct 2020 00:57:55
	System	15 Oct 2020 00:57:55

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:57:20', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d6fc662-6706-47ee-a3b2-d931a9124fe8' User entered 'None (0)'	System	15 Oct 2020 00:57:55
	System	15 Oct 2020 00:57:55

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:57:24', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d6fc662-6706-47ee-a3b2-d931a9124fe8' User entered 'None (0)'	System	15 Oct 2020 00:57:55
	System	15 Oct 2020 00:57:55

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:57:27', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d6fc662-6706-47ee-a3b2-d931a9124fe8' User entered 'None (0)'	System	15 Oct 2020 00:57:55
	System	15 Oct 2020 00:57:55

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:57:33', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d6fc662-6706-47ee-a3b2-d931a9124fe8' User entered 'No (N)'	System	15 Oct 2020 00:57:55
	System	15 Oct 2020 00:57:55

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-14T20:57:54', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7d6fc662-6706-47ee-a3b2-d931a9124fe8' User entered '14 Oct 2020 20:57'	System	15 Oct 2020 00:57:55
	System	15 Oct 2020 00:57:55

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '14 Oct 2020 15:02'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '15 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 2'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:51', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '97507f00-16b5-494d-b2ee-466a0797e34e' User entered 'None (0)'	System	15 Oct 2020 17:10:26
	System	15 Oct 2020 17:10:26

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:54', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '97507f00-16b5-494d-b2ee-466a0797e34e' User entered 'None (0)'	System	15 Oct 2020 17:10:26
	System	15 Oct 2020 17:10:26

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:09:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '97507f00-16b5-494d-b2ee-466a0797e34e' User entered 'None (0)'	System	15 Oct 2020 17:10:26
	System	15 Oct 2020 17:10:26

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:10:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '97507f00-16b5-494d-b2ee-466a0797e34e' User entered 'None (0)'	System	15 Oct 2020 17:10:26
	System	15 Oct 2020 17:10:26

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:10:03', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '97507f00-16b5-494d-b2ee-466a0797e34e' User entered 'None (0)'	System	15 Oct 2020 17:10:26
	System	15 Oct 2020 17:10:26

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:10:06', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '97507f00-16b5-494d-b2ee-466a0797e34e' User entered 'None (0)'	System	15 Oct 2020 17:10:26
	System	15 Oct 2020 17:10:26

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:10:11', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '97507f00-16b5-494d-b2ee-466a0797e34e' User entered 'No (N)'	System	15 Oct 2020 17:10:26
	System	15 Oct 2020 17:10:26

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-15T13:10:23', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '97507f00-16b5-494d-b2ee-466a0797e34e' User entered '15 Oct 2020 13:10'	System	15 Oct 2020 17:10:26
	System	15 Oct 2020 17:10:26

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 3'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8243844d-72d3-4d90-9d7b-f003c77d6b4f' User entered 'None (0)'	System	16 Oct 2020 18:51:46
	System	16 Oct 2020 18:51:46

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:12', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8243844d-72d3-4d90-9d7b-f003c77d6b4f' User entered 'None (0)'	System	16 Oct 2020 18:51:46
	System	16 Oct 2020 18:51:46

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:15', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8243844d-72d3-4d90-9d7b-f003c77d6b4f' User entered 'None (0)'	System	16 Oct 2020 18:51:46
	System	16 Oct 2020 18:51:46

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8243844d-72d3-4d90-9d7b-f003c77d6b4f' User entered 'None (0)'	System	16 Oct 2020 18:51:46
	System	16 Oct 2020 18:51:46

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:21', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8243844d-72d3-4d90-9d7b-f003c77d6b4f' User entered 'None (0)'	System	16 Oct 2020 18:51:46
	System	16 Oct 2020 18:51:46

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:24', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8243844d-72d3-4d90-9d7b-f003c77d6b4f' User entered 'None (0)'	System	16 Oct 2020 18:51:46
	System	16 Oct 2020 18:51:46

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:35', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8243844d-72d3-4d90-9d7b-f003c77d6b4f' User entered 'No (N)'	System	16 Oct 2020 18:51:46
	System	16 Oct 2020 18:51:46

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-16T14:51:43', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8243844d-72d3-4d90-9d7b-f003c77d6b4f' User entered '16 Oct 2020 14:51'	System	16 Oct 2020 18:51:46
	System	16 Oct 2020 18:51:46

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 4'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:21:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd29e9e1c-570a-4512-b8fa-e697445f8cdb' User entered 'None (0)'	System	18 Oct 2020 12:21:24
	System	18 Oct 2020 12:21:24

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:21:03', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd29e9e1c-570a-4512-b8fa-e697445f8cdb' User entered 'None (0)'	System	18 Oct 2020 12:21:24
	System	18 Oct 2020 12:21:24

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:21:07', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd29e9e1c-570a-4512-b8fa-e697445f8cdb' User entered 'None (0)'	System	18 Oct 2020 12:21:24
	System	18 Oct 2020 12:21:24

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:21:11', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd29e9e1c-570a-4512-b8fa-e697445f8cdb' User entered 'None (0)'	System	18 Oct 2020 12:21:24
	System	18 Oct 2020 12:21:24

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:21:13', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd29e9e1c-570a-4512-b8fa-e697445f8cdb' User entered 'None (0)'	System	18 Oct 2020 12:21:24
	System	18 Oct 2020 12:21:24

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:21:16', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd29e9e1c-570a-4512-b8fa-e697445f8cdb' User entered 'None (0)'	System	18 Oct 2020 12:21:24
	System	18 Oct 2020 12:21:24

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:21:19', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd29e9e1c-570a-4512-b8fa-e697445f8cdb' User entered 'No (N)'	System	18 Oct 2020 12:21:24
	System	18 Oct 2020 12:21:24

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-18T08:21:22', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'd29e9e1c-570a-4512-b8fa-e697445f8cdb' User entered '18 Oct 2020 08:21'	System	18 Oct 2020 12:21:24
	System	18 Oct 2020 12:21:24

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '17 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 5'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:42', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bae5663a-2f1d-4410-8fba-03b83340b054' User entered 'None (0)'	System	19 Oct 2020 11:44:12
	System	19 Oct 2020 11:44:12

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:44', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bae5663a-2f1d-4410-8fba-03b83340b054' User entered 'None (0)'	System	19 Oct 2020 11:44:12
	System	19 Oct 2020 11:44:12

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:47', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bae5663a-2f1d-4410-8fba-03b83340b054' User entered 'None (0)'	System	19 Oct 2020 11:44:12
	System	19 Oct 2020 11:44:12

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:51', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bae5663a-2f1d-4410-8fba-03b83340b054' User entered 'None (0)'	System	19 Oct 2020 11:44:12
	System	19 Oct 2020 11:44:12

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:53', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bae5663a-2f1d-4410-8fba-03b83340b054' User entered 'None (0)'	System	19 Oct 2020 11:44:12
	System	19 Oct 2020 11:44:12

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:43:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bae5663a-2f1d-4410-8fba-03b83340b054' User entered 'None (0)'	System	19 Oct 2020 11:44:12
	System	19 Oct 2020 11:44:12

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:44:03', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bae5663a-2f1d-4410-8fba-03b83340b054' User entered 'No (N)'	System	19 Oct 2020 11:44:12
	System	19 Oct 2020 11:44:12

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T07:44:08', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bae5663a-2f1d-4410-8fba-03b83340b054' User entered '19 Oct 2020 07:44'	System	19 Oct 2020 11:44:12
	System	19 Oct 2020 11:44:12

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '18 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 6'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:47', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '102030be-9836-403f-b73e-b1c156a29415' User entered 'None (0)'	System	19 Oct 2020 17:04:20
	System	19 Oct 2020 17:04:20

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:50', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '102030be-9836-403f-b73e-b1c156a29415' User entered 'None (0)'	System	19 Oct 2020 17:04:20
	System	19 Oct 2020 17:04:20

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:53', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '102030be-9836-403f-b73e-b1c156a29415' User entered 'None (0)'	System	19 Oct 2020 17:04:20
	System	19 Oct 2020 17:04:20

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:03:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '102030be-9836-403f-b73e-b1c156a29415' User entered 'None (0)'	System	19 Oct 2020 17:04:20
	System	19 Oct 2020 17:04:20

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '102030be-9836-403f-b73e-b1c156a29415' User entered 'None (0)'	System	19 Oct 2020 17:04:20
	System	19 Oct 2020 17:04:20

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:04:02', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '102030be-9836-403f-b73e-b1c156a29415' User entered 'None (0)'	System	19 Oct 2020 17:04:20
	System	19 Oct 2020 17:04:20

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:04:08', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '102030be-9836-403f-b73e-b1c156a29415' User entered 'No (N)'	System	19 Oct 2020 17:04:20
	System	19 Oct 2020 17:04:20

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-19T13:04:18', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '102030be-9836-403f-b73e-b1c156a29415' User entered '19 Oct 2020 13:04'	System	19 Oct 2020 17:04:20
	System	19 Oct 2020 17:04:20

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '19 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	14 Oct 2020 15:20:04
User entered 'Day 7'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '052a0e31-9be9-408b-90e9-6e28efdb6e96' User entered 'None (0)'	System	20 Oct 2020 16:04:17
	System	20 Oct 2020 16:04:17

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:02:59', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '052a0e31-9be9-408b-90e9-6e28efdb6e96' User entered 'None (0)'	System	20 Oct 2020 16:04:17
	System	20 Oct 2020 16:04:17

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:03:02', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '052a0e31-9be9-408b-90e9-6e28efdb6e96' User entered 'None (0)'	System	20 Oct 2020 16:04:17
	System	20 Oct 2020 16:04:17

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:03:07', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '052a0e31-9be9-408b-90e9-6e28efdb6e96' User entered 'None (0)'	System	20 Oct 2020 16:04:17
	System	20 Oct 2020 16:04:17

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:03:10', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '052a0e31-9be9-408b-90e9-6e28efdb6e96' User entered 'None (0)'	System	20 Oct 2020 16:04:17
	System	20 Oct 2020 16:04:17

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:03:12', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '052a0e31-9be9-408b-90e9-6e28efdb6e96' User entered 'None (0)'	System	20 Oct 2020 16:04:17
	System	20 Oct 2020 16:04:17

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:03:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '052a0e31-9be9-408b-90e9-6e28efdb6e96' User entered 'No (N)'	System	20 Oct 2020 16:04:17
	System	20 Oct 2020 16:04:17

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19F42A1D-C347-4347-B534-A10E49E221BB)', Time: '2020-10-20T12:03:26', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '052a0e31-9be9-408b-90e9-6e28efdb6e96' User entered '20 Oct 2020 12:03'	System	20 Oct 2020 16:04:17
	System	20 Oct 2020 16:04:17

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '20 Oct 2020 12:00'	System	14 Oct 2020 15:20:04

US3662023

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:00:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
User entered '21 Oct 2020 11:59'	System	14 Oct 2020 15:20:04

US3662023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Oct 2020 16:10:38

US3662023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '21 Oct 2020'	Brenda Miller (b) (4)	23 Oct 2020 16:10:38

US3662023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	23 Oct 2020 16:10:38

US3662023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	23 Oct 2020 16:10:38

US3662023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Oct 2020 16:10:45

US3662023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'I'	System	23 Oct 2020 16:10:45

US3662023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 18:50:09

US3662023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '28 Oct 2020'	Brenda Miller (b) (4)	31 Oct 2020 18:50:09

US3662023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	31 Oct 2020 18:50:09

US3662023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	31 Oct 2020 18:50:09

US3662023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	31 Oct 2020 18:50:15

US3662023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'I'	System	31 Oct 2020 18:50:15

US3662023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Nov 2020 17:07:46

US3662023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '04 Nov 2020'	Brenda Miller (b) (4)	08 Nov 2020 17:07:46

US3662023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	08 Nov 2020 17:07:46

US3662023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 17:07:46

US3662023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	08 Nov 2020 17:07:51

US3662023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'I'	System	08 Nov 2020 17:07:51

US3662023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:41:30

US3662023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '12 Nov 2020'	Brenda Miller (b) (4)	16 Nov 2020 17:41:30

US3662023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	16 Nov 2020 17:41:30

US3662023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'VISIT3'	System	16 Nov 2020 17:41:30

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '12 Nov 2020'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '10:07'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '12 Nov 2020 10:07'	System	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '98.0' F	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '65'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'bpm'	System	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'breaths/min'	System	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '124'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '74'	Brenda Miller (b) (4)	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'mmHg'	System	16 Nov 2020 17:42:15

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59

US3662023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59

US3662023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:42:30

US3662023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '12 Nov 2020'	Brenda Miller (b) (4)	16 Nov 2020 17:42:30

US3662023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:42:46

US3662023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User closed query ' Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 12NOV2020. However, test result date is missing in GCL. Please confirm if 12NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 09:37:26
Query ' Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 12NOV2020. However, test result date is missing in GCL. Please confirm if 12NOV2020 is correct date to update in GCL records. ' answered with 'November 12 is the correct date for Day 57 visit' (Site from DM).	Brenda Miller (b) (4) (b) (4)	25 Nov 2020 18:44:26
User opened query ' Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 12NOV2020. However, test result date is missing in GCL. Please confirm if 12NOV2020 is correct date to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:25:29
User entered '12 Nov 2020'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 17:42:46

US3662023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '10:13'	Brenda Miller (b) (4)	16 Nov 2020 17:42:46

US3662023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered '12 Nov 2020 10:13'	System	16 Nov 2020 17:42:46

US3662023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Nov 2020 17:42:52

US3662023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'I'	System	16 Nov 2020 17:42:52

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered 'Day 64'	System	16 Sep 2020 15:22:34

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-11-16T11:09:10', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e8db94c6-0287-40af-8fc8-1cb605c85787'	System	16 Nov 2020 16:10:07
User entered 'Yes (Y)'	System	16 Nov 2020 16:10:07

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-11-16T11:08:13', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e8db94c6-0287-40af-8fc8-1cb605c85787'	System	16 Nov 2020 16:10:07
User entered 'No (N)'	System	16 Nov 2020 16:10:07

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-11-16T11:09:20', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e8db94c6-0287-40af-8fc8-1cb605c85787'	System	16 Nov 2020 16:10:07
User entered 'No (N)'	System	16 Nov 2020 16:10:07

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-11-16T11:09:32', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e8db94c6-0287-40af-8fc8-1cb605c85787'	System	16 Nov 2020 16:10:07
User entered 'No (N)'	System	16 Nov 2020 16:10:07

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-11-16T11:10:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e8db94c6-0287-40af-8fc8-1cb605c85787'	System	16 Nov 2020 16:10:07
User entered '16 Nov 2020 11:10:00'	System	16 Nov 2020 16:10:07

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 15:22:34

US3662023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:18
Data entry locked.	System	16 Sep 2020 15:22:34
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 15:22:34

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2020-11-23T21:42:48', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bd5e99c5-0cd4-4ece-baed-413eaca50fa8'	System	24 Nov 2020 02:43:19
User entered 'No (N)'	System	24 Nov 2020 02:43:19

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2020-11-23T21:42:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bd5e99c5-0cd4-4ece-baed-413eaca50fa8'	System	24 Nov 2020 02:43:19
User entered 'No (N)'	System	24 Nov 2020 02:43:19

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-11-23T21:43:18', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'bd5e99c5-0cd4-4ece-baed-413eaca50fa8'	System	24 Nov 2020 02:43:19
User entered '23 Nov 2020 21:43:18'	System	24 Nov 2020 02:43:19

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2020-11-29T12:13:54', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '34e656a7-a949-4633-ab76-0bf97e30406a'	System	29 Nov 2020 17:14:37
User entered 'No (N)'	System	29 Nov 2020 17:14:37

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2020-11-29T12:14:12', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '34e656a7-a949-4633-ab76-0bf97e30406a'	System	29 Nov 2020 17:14:37
User entered 'No (N)'	System	29 Nov 2020 17:14:37

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-11-29T12:14:34', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '34e656a7-a949-4633-ab76-0bf97e30406a' User entered '29 Nov 2020 12:14:34'	System	29 Nov 2020 17:14:37
	System	29 Nov 2020 17:14:37

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2020-12-04T12:02:06', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'f0a613e5-9e04-4e40-99e9-4642e9eab326'	System	04 Dec 2020 17:02:42
User entered 'No (N)'	System	04 Dec 2020 17:02:42

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2020-12-04T12:02:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'f0a613e5-9e04-4e40-99e9-4642e9eab326'	System	04 Dec 2020 17:02:42
User entered 'No (N)'	System	04 Dec 2020 17:02:42

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-12-04T12:02:36', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'f0a613e5-9e04-4e40-99e9-4642e9eab326'	System	04 Dec 2020 17:02:42
User entered '04 Dec 2020 12:02:36'	System	04 Dec 2020 17:02:42

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2020-12-13T14:25:45', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4aa3da95-f017-4311-a79c-2e040ab0bb88'	System	13 Dec 2020 19:25:53
User entered 'No (N)'	System	13 Dec 2020 19:25:53

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2020-12-13T14:25:48', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4aa3da95-f017-4311-a79c-2e040ab0bb88'	System	13 Dec 2020 19:25:53
User entered 'No (N)'	System	13 Dec 2020 19:25:53

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-12-13T14:25:52', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4aa3da95-f017-4311-a79c-2e040ab0bb88' User entered '13 Dec 2020 14:25:52'	System	13 Dec 2020 19:25:53
	System	13 Dec 2020 19:25:53

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2020-12-18T19:07:56', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7eff9872-b0ee-401a-a984-455df09254ce'	System	19 Dec 2020 00:08:10
User entered 'No (N)'	System	19 Dec 2020 00:08:10

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2020-12-18T19:08:01', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7eff9872-b0ee-401a-a984-455df09254ce'	System	19 Dec 2020 00:08:10
User entered 'No (N)'	System	19 Dec 2020 00:08:10

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2020-12-18T19:08:04', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '7eff9872-b0ee-401a-a984-455df09254ce' User entered '18 Dec 2020 19:08:04'	System	19 Dec 2020 00:08:10
	System	19 Dec 2020 00:08:10

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-01-04T11:16:57', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '63da542b-38cd-4107-a46e-eb70f0c2360e'	System	04 Jan 2021 16:17:09
User entered 'No (N)'	System	04 Jan 2021 16:17:09

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-01-04T11:17:03', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '63da542b-38cd-4107-a46e-eb70f0c2360e'	System	04 Jan 2021 16:17:09
User entered 'No (N)'	System	04 Jan 2021 16:17:09

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-01-04T11:17:06', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '63da542b-38cd-4107-a46e-eb70f0c2360e'	System	04 Jan 2021 16:17:09
User entered '04 Jan 2021 11:17:06'	System	04 Jan 2021 16:17:09

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-01-08T08:57:19', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1955f460-e82d-4e63-84dc-e1f36dd3035b'	System	08 Jan 2021 13:58:16
User entered 'No (N)'	System	08 Jan 2021 13:58:16

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-01-08T08:57:32', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1955f460-e82d-4e63-84dc-e1f36dd3035b'	System	08 Jan 2021 13:58:16
User entered 'Yes (Y)'	System	08 Jan 2021 13:58:16

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-01-08T08:57:54', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1955f460-e82d-4e63-84dc-e1f36dd3035b'	System	08 Jan 2021 13:58:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 13:58:16

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-01-08T08:58:09', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1955f460-e82d-4e63-84dc-e1f36dd3035b'	System	08 Jan 2021 13:58:16
User entered '08 Jan 2021 08:58:09'	System	08 Jan 2021 13:58:16

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-01-15T10:12:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9b06808e-8139-4918-b47c-6e6965c31136'	System	15 Jan 2021 15:12:40
User entered 'No (N)'	System	15 Jan 2021 15:12:40

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-01-15T10:12:36', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9b06808e-8139-4918-b47c-6e6965c31136'	System	15 Jan 2021 15:12:40
User entered 'No (N)'	System	15 Jan 2021 15:12:40

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-01-15T10:12:41', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '9b06808e-8139-4918-b47c-6e6965c31136'	System	15 Jan 2021 15:12:40
User entered '15 Jan 2021 10:12:41'	System	15 Jan 2021 15:12:40

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-01-26T08:29:12', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e5af381d-fcff-4f90-b072-bc7e56ed40fa'	System	26 Jan 2021 13:29:24
User entered 'No (N)'	System	26 Jan 2021 13:29:24

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-01-26T08:29:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e5af381d-fcff-4f90-b072-bc7e56ed40fa'	System	26 Jan 2021 13:29:24
User entered 'No (N)'	System	26 Jan 2021 13:29:24

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-01-26T08:29:22', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'e5af381d-fcff-4f90-b072-bc7e56ed40fa' User entered '26 Jan 2021 08:29:22'	System	26 Jan 2021 13:29:24
	System	26 Jan 2021 13:29:24

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-01-29T00:01:55', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c0fc2b52-a05b-4e10-9e4b-8fec9b8f6bb4'	System	29 Jan 2021 05:02:24
User entered 'No (N)'	System	29 Jan 2021 05:02:24

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-01-29T00:01:58', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c0fc2b52-a05b-4e10-9e4b-8fec9b8f6bb4'	System	29 Jan 2021 05:02:24
User entered 'No (N)'	System	29 Jan 2021 05:02:24

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-01-29T00:02:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: 'c0fc2b52-a05b-4e10-9e4b-8fec9b8f6bb4'	System	29 Jan 2021 05:02:24
User entered '29 Jan 2021 00:02:00'	System	29 Jan 2021 05:02:24

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-02-05T07:59:17', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '46e348e6-980e-4460-9026-3781aaecfe1b'	System	05 Feb 2021 12:59:22
User entered 'No (N)'	System	05 Feb 2021 12:59:22

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-02-05T07:59:20', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '46e348e6-980e-4460-9026-3781aaecfe1b'	System	05 Feb 2021 12:59:22
User entered 'No (N)'	System	05 Feb 2021 12:59:22

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-02-05T07:59:25', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '46e348e6-980e-4460-9026-3781aacefe1b'	System	05 Feb 2021 12:59:22
User entered '05 Feb 2021 07:59:25'	System	05 Feb 2021 12:59:22

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-02-12T06:14:25', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '36ad2425-99a3-4ba9-bad6-5607cf822814'	System	12 Feb 2021 11:14:35
User entered 'No (N)'	System	12 Feb 2021 11:14:35

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-02-12T06:14:29', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '36ad2425-99a3-4ba9-bad6-5607cf822814'	System	12 Feb 2021 11:14:35
User entered 'No (N)'	System	12 Feb 2021 11:14:35

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-02-12T06:14:31', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '36ad2425-99a3-4ba9-bad6-5607cf822814'	System	12 Feb 2021 11:14:35
User entered '12 Feb 2021 06:14:31'	System	12 Feb 2021 11:14:35

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-02-19T09:14:55', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8e1f4bc0-15b1-48b1-b9e3-90ca0550dfdd'	System	19 Feb 2021 14:15:11
User entered 'No (N)'	System	19 Feb 2021 14:15:11

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-02-19T09:14:43', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8e1f4bc0-15b1-48b1-b9e3-90ca0550dfdd'	System	19 Feb 2021 14:15:11
User entered 'No (N)'	System	19 Feb 2021 14:15:11

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-02-19T09:15:08', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8e1f4bc0-15b1-48b1-b9e3-90ca0550dfdd'	System	19 Feb 2021 14:15:11
User entered '19 Feb 2021 09:15:08'	System	19 Feb 2021 14:15:11

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-02-26T00:01:50-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8fedd500-d956-4177-b1a5-7cb2973ca0eb' User entered 'No (N)'	System	26 Feb 2021 05:03:03
	System	26 Feb 2021 05:03:03

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-02-26T00:01:56-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8fedd500-d956-4177-b1a5-7cb2973ca0eb' User entered 'No (N)'	System	26 Feb 2021 05:03:03

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-02-26T00:02:00-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8fedd500-d956-4177-b1a5-7cb2973ca0eb' User entered '26 Feb 2021 00:02:00'	System	26 Feb 2021 05:03:03
	System	26 Feb 2021 05:03:03

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-03-09T08:26:48-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '66a562c4-56e2-468b-9709-7b217502c90c'	System	09 Mar 2021 13:27:32
User entered 'No (N)'	System	09 Mar 2021 13:27:32

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-03-09T08:26:58-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '66a562c4-56e2-468b-9709-7b217502c90c'	System	09 Mar 2021 13:27:32
User entered 'No (N)'	System	09 Mar 2021 13:27:32

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-03-09T08:27:28-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '66a562c4-56e2-468b-9709-7b217502c90c'	System	09 Mar 2021 13:27:32
User entered '09 Mar 2021 08:27:28'	System	09 Mar 2021 13:27:32

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-03-12T23:43:56-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '99c44ce1-ce73-4c93-8925-81ca428cf721' User entered 'No (N)'	System	13 Mar 2021 04:44:08
	System	13 Mar 2021 04:44:08

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-03-12T23:43:59-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '99c44ce1-ce73-4c93-8925-81ca428cf721'	System	13 Mar 2021 04:44:08
User entered 'No (N)'	System	13 Mar 2021 04:44:08

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-03-12T23:44:02-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '99c44ce1-ce73-4c93-8925-81ca428cf721'	System	13 Mar 2021 04:44:08
User entered '12 Mar 2021 23:44:02'	System	13 Mar 2021 04:44:08

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-03-23T13:11:52-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1261646e-52a0-4aae-850a-8a16274b1b42'	System	23 Mar 2021 17:13:08
User entered 'No (N)'	System	23 Mar 2021 17:13:08

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-03-23T13:11:55-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1261646e-52a0-4aae-850a-8a16274b1b42'	System	23 Mar 2021 17:13:08
User entered 'No (N)'	System	23 Mar 2021 17:13:08

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-03-23T13:11:57-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1261646e-52a0-4aae-850a-8a16274b1b42'	System	23 Mar 2021 17:13:08
User entered '23 Mar 2021 13:11:57'	System	23 Mar 2021 17:13:08

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-03-26T00:01:42-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2f8f0995-510b-41fd-a8f5-fb1127dcd6c1'	System	26 Mar 2021 04:03:32
User entered 'No (N)'	System	26 Mar 2021 04:03:32

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-03-26T00:01:45-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2f8f0995-510b-41fd-a8f5-fb1127dcd6c1'	System	26 Mar 2021 04:03:32
User entered 'No (N)'	System	26 Mar 2021 04:03:32

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-03-26T00:01:48-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2f8f0995-510b-41fd-a8f5-fb1127dcd6c1' User entered '26 Mar 2021 00:01:48'	System	26 Mar 2021 04:03:32

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-04-02T14:09:08-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2d417402-dcd4-4a1e-adee-fefe51f792c2'	System	02 Apr 2021 18:09:18
User entered 'No (N)'	System	02 Apr 2021 18:09:18

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-04-02T14:09:11-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2d417402-dcd4-4a1e-adee-fefe51f792c2'	System	02 Apr 2021 18:09:18
User entered 'No (N)'	System	02 Apr 2021 18:09:18

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-04-02T14:09:15-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '2d417402-dcd4-4a1e-adee-fefe51f792c2'	System	02 Apr 2021 18:09:18
User entered '02 Apr 2021 14:09:15'	System	02 Apr 2021 18:09:18

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-04-16T13:30:46-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4223da9b-c26d-4155-9b6a-3318f80d3c48'	System	16 Apr 2021 17:33:15
User entered 'No (N)'	System	16 Apr 2021 17:33:15

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-04-16T13:30:49-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4223da9b-c26d-4155-9b6a-3318f80d3c48'	System	16 Apr 2021 17:33:15
User entered 'No (N)'	System	16 Apr 2021 17:33:15

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-04-16T13:30:53-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '4223da9b-c26d-4155-9b6a-3318f80d3c48'	System	16 Apr 2021 17:33:15
User entered '16 Apr 2021 13:30:53'	System	16 Apr 2021 17:33:15

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-04-27T16:49:51-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '721d63b8-add3-42ed-91ed-9f812d1ec3e7'	System	28 Apr 2021 21:46:50
User entered 'No (N)'	System	28 Apr 2021 21:46:50

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-04-27T16:49:55-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '721d63b8-add3-42ed-91ed-9f812d1ec3e7'	System	28 Apr 2021 21:46:50
User entered 'No (N)'	System	28 Apr 2021 21:46:50

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-04-27T16:50:00-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '721d63b8-add3-42ed-91ed-9f812d1ec3e7'	System	28 Apr 2021 21:46:50
User entered '27 Apr 2021 16:50:00'	System	28 Apr 2021 21:46:50

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[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 (d54e240b3f2a5f62)', Time: '2021-05-01T16:52:18-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8aba0773-dad3-4264-8007-5780912356d3'	System	01 May 2021 20:52:58
User entered 'No (N)'	System	01 May 2021 20:52:58

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Have you been exposed to someone with 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 (d54e240b3f2a5f62)', Time: '2021-05-01T16:52:20-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8aba0773-dad3-4264-8007-5780912356d3'	System	01 May 2021 20:52:58
User entered 'No (N)'	System	01 May 2021 20:52:58

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-05-01T16:52:24-04:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '8aba0773-dad3-4264-8007-5780912356d3'	System	01 May 2021 20:52:58
User entered '01 May 2021 16:52:24'	System	01 May 2021 20:52:58

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:07:12

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Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

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Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:07:12

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Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 19:07:12

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:07:12

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '04 Nov 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '08 Nov 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '11 Nov 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '15 Nov 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '18 Nov 2022 00:01'	System	19 Nov 2020 19:07:12

US3662023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:07:12
Amendment Manager: User entered '22 Nov 2022 23:59'	System	19 Nov 2020 19:07:12

US3662023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:00:46

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 01:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-03-05T08:22:10-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1a5ba6dc-d895-4fa2-964b-ae9725c4d31e'	System	05 Mar 2021 13:22:17
User entered 'No (N)'	System	05 Mar 2021 13:22:17

US3662023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:00:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d54e240b3f2a5f62)', Time: '2021-03-05T08:22:13-05:00', User OID: 'PatientReportedOutcome (US3662023)', ODM File OID: '1a5ba6dc-d895-4fa2-964b-ae9725c4d31e' User entered '05 Mar 2021 08:22:13'	System	05 Mar 2021 13:22:17
	System	05 Mar 2021 13:22:17

US3662023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Dec 2020 14:23:22

US3662023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '8 Dec 2020'	Angela Snyder (b) (4)	09 Dec 2020 14:23:22

US3662023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	09 Dec 2020 14:23:22

US3662023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	09 Dec 2020 14:23:22

US3662023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Dec 2020 14:23:27

US3662023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:07:59
User entered 'I'	System	09 Dec 2020 14:23:27

US3662023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User closed query 'Per protocol regularly scheduled safety calls are suspended while subject in convalescent phase. Please remove data from Safety Call Day 119. Thank you. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:29:52
Query 'Per protocol regularly scheduled safety calls are suspended while subject in convalescent phase. Please remove data from Safety Call Day 119. Thank you. ' answered with 'updated' (Site from CRA).	michelle saemann (b) (4) (b) (4)	01 Feb 2021 13:31:34
User entered 'No (N)' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	01 Feb 2021 13:31:25
User opened query 'Per protocol regularly scheduled safety calls are suspended while subject in convalescent phase. Please remove data from Safety Call Day 119. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 16:07:46
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	12 Jan 2021 13:29:12

US3662023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty; reason for change Data Entry Error	(b) (4) michelle saemann (b) (4)	01 Feb 2021 13:31:25
User entered '11 Jan 2021'	Angela Snyder (b) (4)	12 Jan 2021 13:29:12
	(b) (4)	

US3662023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	01 Feb 2021 13:31:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Angela Snyder (b) (4)	12 Jan 2021 13:29:12
	(b) (4)	

US3662023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	12 Jan 2021 13:29:12

US3662023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	12 Jan 2021 13:29:16

US3662023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User entered '1'	System	12 Jan 2021 13:29:16

US3662023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
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	12 Feb 2021 14:09:55
User entered 'Yes (Y)' reason for change: Data Entry Error	System	12 Feb 2021 14:09:55
User opened query 'Data is required. Please complete.' (Site from System).	Angela Snyder (b) (4)	12 Feb 2021 14:09:55
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	System	08 Feb 2021 20:31:09
	Angela Snyder (b) (4)	08 Feb 2021 20:31:09
	(b) (4)	
	Angela Snyder (b) (4)	08 Feb 2021 19:41:24
	(b) (4)	

US3662023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '12 Feb 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	12 Feb 2021 14:09:55
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Feb 2021 20:31:09
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	08 Feb 2021 20:31:09
User entered empty; reason for change Data Entry Error	Angela Snyder (b) (4)	08 Feb 2021 20:31:09
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	08 Feb 2021 19:41:24
User entered '5 Feb 2021'	Angela Snyder (b) (4)	08 Feb 2021 19:41:24

US3662023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Angela Snyder (b) (4)	12 Feb 2021 14:09:55
User entered empty; reason for change Data Entry	(b) (4)	
Error	Angela Snyder (b) (4)	08 Feb 2021 20:31:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Angela Snyder (b) (4)	08 Feb 2021 19:41:24
	(b) (4)	

US3662023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 19:41:24

US3662023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
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	09 Feb 2021 14:45:40
User entered 'Yes (Y)' reason for change: Data Entry Error	System	09 Feb 2021 14:45:40
User opened query 'Data is required. Please complete.' (Site from System).	Angela Snyder (b) (4)	09 Feb 2021 14:45:40
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	System	08 Feb 2021 20:31:25
	Angela Snyder (b) (4)	08 Feb 2021 20:31:25
	(b) (4)	
	Angela Snyder (b) (4)	08 Feb 2021 19:41:45
	(b) (4)	

US3662023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User entered '1'	System	09 Feb 2021 14:45:40
User entered empty.	System	08 Feb 2021 20:31:25
User entered '1'	System	08 Feb 2021 19:41:45

US3662023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Mar 2021 13:03:05

US3662023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '12 Mar 2021'	Angela Snyder (b) (4)	15 Mar 2021 13:03:05

US3662023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	15 Mar 2021 13:03:05

US3662023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered empty.	Angela Snyder (b) (4)	15 Mar 2021 13:03:05

US3662023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Mar 2021 13:03:10

US3662023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:45:51
User entered '1'	System	15 Mar 2021 13:03:10

US3662023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 18:02:26
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '16 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 18:02:26
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
User entered 'Clinic (Clinic)'	(b) (4) Angela Snyder (b) (4)	16 Apr 2021 18:02:26
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	16 Apr 2021 18:02:26

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '16 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '12:15'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Apr 2021 12:15'	System	16 Apr 2021 18:03:02

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '97.4' F	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered 'Other (Other)'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered 'infrared thermometer'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '56'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Apr 2021 18:03:02

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '16'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Apr 2021 18:03:02

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '113'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 18:03:02

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '71'	Angela Snyder (b) (4)	16 Apr 2021 18:03:02
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 18:03:02

US3662023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	16 Apr 2021 18:03:10
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	16 Apr 2021 18:03:10
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 18:03:23
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '16 Apr 2021'	Angela Snyder (b) (4)	16 Apr 2021 18:03:23
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered '12:25'	Angela Snyder (b) (4)	16 Apr 2021 18:03:23
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Apr 2021 12:25'	System	16 Apr 2021 18:03:23

US3662023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:13
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	16 Apr 2021 18:03:28
	(b) (4)	

US3662023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 18:03:28

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:30:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:58:42
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:47:29

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:30:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:58:42
User entered '09:08'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:47:29

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:30:45
User entered '8 Jan 2021 09:08'	System	11 Jan 2021 16:47:29

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:30:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:58:42
User entered 'Safety Call (Safety Call)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:47:29

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:30:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:58:42
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:47:29

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 1 (Day 1)'	Angela Snyder (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User closed query 'Per ETRTR: Please consider adding Symptoms prior to 07Jan21, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 18:27:57
Query 'Per ETRTR: Please consider adding Symptoms prior to 07Jan21, thanks.' answered with 'symptoms began on 1.7.21, nothing to report prior' (Site from CRA).	MaKayla Bishop (b) (4)	01 Feb 2021 14:54:10
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User opened query 'Per ETRTR: Please consider adding Symptoms prior to 07Jan21, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 18:31:01
User entered '7 Jan 2021'	Angela Snyder (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '100.1' F	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:48:44

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 2 (Day 2)'	Angela Snyder (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97.5' F	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:49:48

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 3 (Day 3)'	Angela Snyder (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '9 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '99.1' F	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:50:31

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 4 (Day 4)'	Angela Snyder (b) (4)	11 Jan 2021 16:51:30

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '10 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '95'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '99.1' F	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:51:30

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 5 (Day 5)'	Angela Snyder (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '11 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '95'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '99.1' F	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:27

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 6 (Day 6)'	Angela Snyder (b) (4)	13 Jan 2021 13:54:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '12 Jan 2021'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '98'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '100.1' F	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:20:47
User closed query 'Per log on 13Jan21 subject was positive for this symptom. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 18:28:17
Query 'Per log on 13Jan21 subject was positive for this symptom. Please verify and update as needed. ' answered with 'updated' (Site from CRA).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 14:50:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 14:50:27
User opened query 'Per log on 13Jan21 subject was positive for this symptom. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 15:13:07
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:13
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:20:49
User closed query 'Per log on 13Jan21 subject was positive for this symptom. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 18:28:19
Query 'Per log on 13Jan21 subject was positive for this symptom. Please verify and update as needed. ' answered with 'updated. ' (Site from CRA).	MaKayla Bishop (b) (4)	01 Feb 2021 14:50:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 14:50:27
User opened query 'Per log on 13Jan21 subject was positive for this symptom. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 15:13:13
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:14
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 7 (Day 7)'	Angela Snyder (b) (4)	13 Jan 2021 20:22:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '13 Jan 2021'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '98'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '98.7' F	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Severe (Severe)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 20:22:46

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 8 (Day 8)'	Angela Snyder (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '14 Jan 2021'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '93'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '98.7' F	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 13:36:01

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 9 (Day 9)'	Angela Snyder (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '15 Jan 2021'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '93'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '98.2' F	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:06

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 10 (Day 10)'	Angela Snyder (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '16 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97.8' F	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:53:39

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 11 (Day 11)'	Angela Snyder (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '17 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '95'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97.8' F	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 12 (Day 12)'	Angela Snyder (b) (4)	19 Jan 2021 16:54:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '18 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '98'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	19 Jan 2021 16:54:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97.1' F	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:54:59

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 13 (Day 13)'	Angela Snyder (b) (4)	19 Jan 2021 18:26:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '19 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '98'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	19 Jan 2021 18:26:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97.9' F	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 18:26:21

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 14 (Day 14)'	Angela Snyder (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:22:46
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '20 Jan 2021'	Angela Snyder (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User closed query 'Assessment marked not done, however note in source states patient "feels great and is having no symptoms." Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 18:28:37
Query 'Assessment marked not done, however note in source states patient "feels great and is having no symptoms." Please verify and update if needed. ' answered with 'updated. ' (Site from CRA).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 15:04:22
User entered '0' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 15:04:09
User opened query 'Assessment marked not done, however note in source states patient "feels great and is having no symptoms." Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 16:16:59
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:40
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:32
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '1'	Angela Snyder (b) (4) (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered '97' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:03:07
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	01 Feb 2021 15:03:07
User entered empty.	System	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered '97.7' F reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:03:07
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4) (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4) (b) (4)	21 Jan 2021 17:50:54

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4) (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4) (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4) (b) (4)	21 Jan 2021 17:50:54

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4) (b) (4)	21 Jan 2021 17:50:54

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:22:46
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	01 Feb 2021 15:04:09
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 16:15:52
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:50:54

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 15 (Day 15)'	Angela Snyder (b) (4)	22 Jan 2021 11:57:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '21 Jan 2021'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '96'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '98.2' F	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:57:40

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Day 16 (Day 16)'	Angela Snyder (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '22 Jan 2021'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User entered '%'	System	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered '97.4' F	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:00:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:02
User entered 'None (None)'	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 20:02:19

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User closed query 'Please file signed lab report in subject source binder. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 18:26:50
Query 'Please file signed lab report in subject source binder. ' answered with 'done' (Site from CRA).	MaKayla Bishop (b) (4)	01 Feb 2021 14:52:15
User opened query 'Please file signed lab report in subject source binder. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:20:44
User entered '8 Jan 2021'	michelle saemann (b) (4)	20 Jan 2021 19:10:04
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[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 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:10:04

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[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 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 05:18:26
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Confirmed. Diagnosis was entered on 1/11/2021' (Site from System).	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:00
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	20 Jan 2021 19:10:04
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:10:04

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User entered '8 Jan 2021'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:10:04

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:10:04

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:10:04

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[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 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:10:04

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:10:04

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:03
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:10:04

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:24
User entered 'I'	System	20 Jan 2021 19:10:04

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:08:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:44:25
User closed query 'Per CDM: Per sponsor review, symptom log indicates multiple days with low SpO2 . Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 07:23:25
Query 'Per CDM: Per sponsor review, symptom log indicates multiple days with low SpO2 . Please review and reconcile.' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	30 Mar 2021 11:47:09
DataPoint Un-verified.	Angela Snyder (b) (4) (b) (4)	30 Mar 2021 11:46:25
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	30 Mar 2021 11:46:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	30 Mar 2021 11:46:25
User opened query 'Per CDM: Per sponsor review, symptom log indicates multiple days with low SpO2 . Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:19:58
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:00
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:44:25
DataPoint Un-verified.	(b) (4)	
	Angela Snyder (b) (4)	30 Mar 2021 11:46:25
Signature has been broken.	(b) (4)	
	Angela Snyder (b) (4)	30 Mar 2021 11:46:25
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	30 Mar 2021 11:46:25
User signature succeeded.	(b) (4)	
	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4)	20 Jan 2021 20:00:16
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:01
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:44:25
DataPoint Un-verified.	(b) (4)	
	Angela Snyder (b) (4)	30 Mar 2021 11:46:25
Signature has been broken.	(b) (4)	
	Angela Snyder (b) (4)	30 Mar 2021 11:46:25
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	30 Mar 2021 11:46:25
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.		
	michelle saemann (b) (4)	20 Jan 2021 20:00:16
	(b) (4)	

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Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:44:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '93' reason for change: Data Entry Error	System	30 Mar 2021 11:46:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Angela Snyder (b) (4)	30 Mar 2021 11:46:51
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	System	30 Mar 2021 11:46:25
User entered '93.' (non-conformant).	Angela Snyder (b) (4)	30 Mar 2021 11:46:25
User signature succeeded.	(b) (4)	
DataPoint Verified.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 15:24:56
	michelle saemann (b) (4)	20 Jan 2021 20:00:16
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:24:56
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 20:00:16

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 23:00:46

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:25:00
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	27 Jan 2021 17:20:23

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:58:47
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:13:12

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:58:47
User entered '09:08'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:13:12

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:08
User entered '8 Jan 2021 09:08'	System	11 Jan 2021 19:13:12

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:58:47
User entered 'Safety Call (Safety Call)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:13:12

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:46

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:58:47
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:13:12

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[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 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[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 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 03:19:31
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Confirmed' (Site from System).	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:16:50
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	11 Jan 2021 19:15:26
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

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Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[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 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User entered 'UC Health Lab'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:27:02
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:00:46

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:40
User entered 'I'	System	11 Jan 2021 19:15:26

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'duplicate form' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:26:03
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:28:31
DataPoint Un-verified.	System	
Signature has been broken.	System	
User entered empty; reason for change Data Entry Error	System	
User signature succeeded.	System	
DataPoint Verified.	System	
User entered 'No (N)'	System	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4)	20 Jan 2021 19:49:36

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'duplicate form' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:26:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:28:31
DataPoint Un-verified.	System	
Signature has been broken.	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	michelle saemann (b) (4)	03 Mar 2021 19:28:31
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	michelle saemann (b) (4)	03 Mar 2021 19:28:31
	(b) (4)	
	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:25:17
	(b) (4)	
	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4)	20 Jan 2021 19:49:36

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'duplicate form' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:26:08
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:28:31
DataPoint Un-verified.	System	
Signature has been broken.	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	michelle saemann (b) (4)	03 Mar 2021 19:28:31
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	michelle saemann (b) (4)	03 Mar 2021 19:28:31
	(b) (4)	
	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:25:17
	(b) (4)	
	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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[End Date](#)

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User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'duplicate form' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:26:11
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:28:31
DataPoint Un-verified.	System	
Signature has been broken.	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	michelle saemann (b) (4)	03 Mar 2021 19:28:31
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	michelle saemann (b) (4)	03 Mar 2021 19:28:31
	(b) (4)	
	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:25:17
	(b) (4)	
	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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User entered empty.	michelle saemann (b) (4)	20 Jan 2021 19:49:36

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4)	20 Jan 2021 19:49:36

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'duplicate form' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:26:37
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:28:31
DataPoint Un-verified.	System	
Signature has been broken.	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
User signature succeeded.	michelle saemann (b) (4)	03 Mar 2021 19:28:31
DataPoint Verified.	(b) (4)	
User entered 'No (N)'	michelle saemann (b) (4)	03 Mar 2021 19:28:31
	(b) (4)	
	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
	(b) (4), (b) (6)	09 Feb 2021 20:25:17
	(b) (4)	
	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'duplicate form' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:26:31
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:28:31
DataPoint Un-verified.	System	
Signature has been broken.	System	
User entered empty; reason for change Data Entry Error	System	
User signature succeeded.	System	
DataPoint Verified.	System	
User entered 'No (N)'	System	

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User entered empty.	michelle saemann (b) (4)	20 Jan 2021 19:49:36

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered 'No (N)'	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
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User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered 'No (N)'	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
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[ECMO?](#)

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	michelle saemann (b) (4)	03 Mar 2021 19:28:31
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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
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[Evidence of Shock Requires
Vasopressors](#)

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DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
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	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered 'No (N)'	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
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User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered 'No (N)'	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered 'No (N)'	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered 'No (N)'	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered 'No (N)'	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Un-verified.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
Signature has been broken.	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	03 Mar 2021 19:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered 'No (N)'	michelle saemann (b) (4)	20 Jan 2021 19:49:36
	(b) (4)	

US3662023

Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4)	20 Jan 2021 19:49:36

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'duplicate form' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 08:26:41
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 19:28:31
DataPoint Un-verified.	System	
Signature has been broken.	System	
User entered empty; reason for change Data Entry Error	System	
User signature succeeded.	System	
DataPoint Verified.	System	
User entered 'No (N)'	System	

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

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Folder: Covid-19 Assessment 08 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 23:00:46

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:32:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 20:25:17
User entered empty.	michelle saemann (b) (4) (b) (4)	20 Jan 2021 19:49:36

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:00:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User closed query 'Please file all signed Saliva sample reports in subject source binder when received. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 18:03:36
Query 'Please file all signed Saliva sample reports in subject source binder when received. ' answered with 'attempting to resolve ppd query. will file when result is available ' (Site from CRA).	MaKayla Bishop (b) (4)	01 Feb 2021 14:55:39
User opened query 'Please file all signed Saliva sample reports in subject source binder when received. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 15:23:48
User accepted default value 'Day 3 (Day 3)'	Angela Snyder (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:00:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:15:38
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:15:38
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:14:55
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'attempting to resolve ppd query ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 14:56:04
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:41:48
Data hard unlocked.	(b) (4), (b) (6)	01 Feb 2021 06:41:44
Data hard locked.	(b) (4), (b) (6)	01 Feb 2021 06:41:42
User entered '11 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:00:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User accepted default value 'Day 5 (Day 5)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:00:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:15:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:49
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:15:56
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:14:37
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'result is in PPD, please check. accession number 1f60jfb' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 14:56:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:41:56
User entered '12 Jan 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:49
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:00:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User accepted default value 'Day 7 (Day 7)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:00:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:16:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:46
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:16:20
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:14:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'attempting to resolve ppd query.' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 14:57:08
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:42:03
User entered '14 Jan 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:46
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:00:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User accepted default value 'Day 9 (Day 9)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:00:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:16:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:46
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:16:30
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:14:26
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'attempting to resolve ppd query. ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 14:57:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:42:11
User entered '15 Jan 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 20:24:46
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:00:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User accepted default value 'Day 14 (Day 14)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:00:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:17:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:56:36
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:17:09
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:14:15
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'attempting to resolve ppd query.' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 14:57:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 06:42:19
User entered '21 Jan 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Jan 2021 11:56:36
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:00:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User accepted default value 'Day 21 (Day 21)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:00:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
User closed query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 28-Jan-21 is reported in PPD central lab with Day7 with Accession # 1F635861082. Please review the Accession # in Preclarus and confirm the Sample label in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM). Query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 28-Jan-21 is reported in PPD central lab with Day7 with Accession # 1F635861082. Please review the Accession # in Preclarus and confirm the Sample label in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'Correct as entered into EDC. Per (b) (6) via email: Day 21 Accession # 1F635861082, Day 7 accession # IF6400038928 This has not been updated in Preclarus. I am not sure if they are able to update Preclarus. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 06:51:06
	michelle saemann (b) (4)	22 Apr 2021 15:28:46
	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 20:17:26
User opened query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 28-Jan-21 is reported in PPD central lab with Day7 with Accession # 1F635861082. Please review the Accession # in Preclarus and confirm the Sample label in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 13:18:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Feb 2021 20:17:45
User entered 'No (N)'	Angela Snyder (b) (4)	11 Jan 2021 20:29:52
	(b) (4)	

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:17:26
User entered '28 Jan 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Feb 2021 20:17:45
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:00:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User accepted default value 'Day 28 (Day 28)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:00:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:17:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:17:45
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:38:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:17:41
User entered '5 Feb 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Feb 2021 20:17:45
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	11 Jan 2021 20:29:52

US3662023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:51:30
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:52:15

US3662023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:51:30
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:52:15

US3662023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[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 10:33:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:51:30
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:52:15

US3662023

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:34
User entered 'SICKD1'	System	11 Jan 2021 16:52:15

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '11:10'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User entered '8 Jan 2021 11:10'	System	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '168.91' cm	Angela Snyder (b) (4)	11 Jan 2021 16:53:32
DataPoint set to visible.	(b) (4) System	11 Jan 2021 16:52:15

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '71.39' kg	Angela Snyder (b) (4)	11 Jan 2021 16:53:32
DataPoint set to visible.	(b) (4) System	11 Jan 2021 16:52:15

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '97.9' F	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered 'Other (Other)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered 'infrared thermometer'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '74'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User entered 'bpm'	System	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '16'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User entered 'breaths/min'	System	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '104'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User entered 'mmHg'	System	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:52:00
User entered '64'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43
User entered 'mmHg'	System	11 Jan 2021 16:53:32

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43

US3662023

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:43

US3662023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:54:33
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:48

US3662023

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:54:33
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:53:48

US3662023

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 23:00:46

[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 10:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:54:43
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:54:09

US3662023

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 08 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 18:10:02
Query 'Per Lab Recon: SARS-COV2: Sample dated 08 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with '1F60JFV 1F60JFV see above accession numbers which are shown in preclarus ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	01 Feb 2021 15:00:21
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 14:54:43
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 08 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:52:35

US3662023

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '8 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:54:09

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:08:29
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:15:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:08:29
User entered '5 Feb 2021'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:15:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[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 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:08:29
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:15:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User entered 'SICKD28'	System	08 Feb 2021 20:15:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:16:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 20:16:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:17
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 20:16:11
User entered empty.	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '5 Feb 2021'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '08:15'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User entered '5 Feb 2021 08:15'	System	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '171.25' cm	Angela Snyder (b) (4)	08 Feb 2021 20:16:11
DataPoint set to visible.	(b) (4) System	08 Feb 2021 20:15:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '72.03' kg	Angela Snyder (b) (4)	08 Feb 2021 20:16:11
DataPoint set to visible.	(b) (4) System	08 Feb 2021 20:15:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '97.8' F	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered 'Other (Other)'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered 'infrared thermometer'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '51'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User entered 'bpm'	System	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '12'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User entered 'breaths/min'	System	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '117'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User entered 'mmHg'	System	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:28
User entered '65'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User entered 'mmHg'	System	08 Feb 2021 20:16:11

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:10:20
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:29

US3662023

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:10:20
User entered '5 Feb 2021'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:29

US3662023

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 23:00:46

[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 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:35
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:47

US3662023

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 23:00:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:28:31
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:35
User entered '5 Feb 2021'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:16:47

US3662023

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

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Jan 2021 15:18:32

US3662023

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

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Jan 2021'	Angela Snyder (b) (4)	05 Jan 2021 15:18:32

US3662023

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

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[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 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	05 Jan 2021 15:18:32

US3662023

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

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 15:18:32

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Jan 2021'	(b) (4) MaKayla Bishop (b) (4)	05 Jan 2021 13:25:04

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[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 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:06:32

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	MaKayla Bishop (b) (4)	05 Jan 2021 13:25:04

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:06:32

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Jan 2021'	(b) (4) MaKayla Bishop (b) (4)	05 Jan 2021 13:25:04

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	05 Jan 2021 13:25:04

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:30:32
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	05 Jan 2021 13:25:04
	(b) (4)	

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:30:32
User entered 'Placebo (Placebo)'	MaKayla Bishop (b) (4)	05 Jan 2021 13:25:04
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	MaKayla Bishop (b) (4)	05 Jan 2021 13:25:04

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '1'	System	05 Jan 2021 13:25:04

US3662023

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

Form: Unblinding

Generated On: 11 Aug 2021 23:00:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'I'	System	05 Jan 2021 13:25:04

US3662023

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '169.16' cm	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '72.75' kg	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '25.42363'	System	05 Jan 2021 17:02:13
DataPoint set to visible.	System	05 Jan 2021 13:25:04

US3662023

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '169.16' cm	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '72.75' kg	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '25.42363'	System	05 Jan 2021 17:02:13
DataPoint set to visible.	System	05 Jan 2021 13:25:04

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User accepted default value 'Pre-Dose (PREDOSE)'	Angela Snyder (b) (4) (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Jan 2021'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '07:57'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '5 Jan 2021 07:57'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '97.6' F	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'infrared thermometer'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '56'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'bpm'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'breaths/min'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '125'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'mmHg'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '68'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'mmHg'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '169.16' cm	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '72.75' kg	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:00:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '25.42363'	System	05 Jan 2021 17:02:13
DataPoint set to visible.	System	05 Jan 2021 13:25:04

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User accepted default value 'Post-Dose (POSTDOSE)'	Angela Snyder (b) (4) (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Jan 2021'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '09:04'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '5 Jan 2021 09:04'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '97.9' F	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'infrared thermometer'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '50'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'bpm'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'breaths/min'	System	05 Jan 2021 17:02:13

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '114'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'mmHg'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '76'	Angela Snyder (b) (4)	05 Jan 2021 17:02:13

US3662023

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'mmHg'	System	05 Jan 2021 17:02:13

US3662023

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

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 19:42:48

US3662023

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

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Jan 2021'	Angela Snyder (b) (4)	08 Feb 2021 19:42:48

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	MaKayla Bishop (b) (4)	05 Jan 2021 13:36:29

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	05 Jan 2021 13:36:29

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

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 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	(b) (4) MaKayla Bishop (b) (4)	05 Jan 2021 13:36:29

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'mRNA-1273'	System	05 Jan 2021 13:36:29
DataPoint set to visible.	System	05 Jan 2021 13:25:04

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Jan 2021'	MaKayla Bishop (b) (4)	05 Jan 2021 13:36:29

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '08:34'	MaKayla Bishop (b) (4)	05 Jan 2021 13:36:29

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '5 Jan 2021 08:34'	System	05 Jan 2021 13:36:29

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4)	05 Jan 2021 13:36:29

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'ONCE'	System	05 Jan 2021 13:36:29

US3662023

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

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 13:36:29

US3662023

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Jan 2021 17:02:33

US3662023

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 05JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 05JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:08:08
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 05JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 05JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 15:29:13
User entered '5 Jan 2021'	Angela Snyder (b) (4) (b) (4)	05 Jan 2021 17:02:33

US3662023

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '08:25'	Angela Snyder (b) (4)	05 Jan 2021 17:02:33

US3662023

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '5 Jan 2021 08:25'	System	05 Jan 2021 17:02:33

US3662023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Jan 2021 17:02:45

US3662023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:00:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Jan 2021'	Angela Snyder (b) (4)	05 Jan 2021 17:02:45

US3662023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '08:20'	Angela Snyder (b) (4)	05 Jan 2021 17:02:45

US3662023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:00:46

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered '5 Jan 2021 08:20'	System	05 Jan 2021 17:02:45

US3662023

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

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Jan 2021 17:02:50

US3662023

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

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:14
User entered 'I'	System	05 Jan 2021 17:02:50

US3662023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'No (N)'	Angela Snyder (b) (4)	08 Feb 2021 20:11:48

US3662023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:11:48

US3662023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:11:48

US3662023

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'OL day 8 safety call not done. Patient in convalescence phase'	Angela Snyder (b) (4)	08 Feb 2021 20:11:48

US3662023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:34
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:11:54

US3662023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:34
User entered 'I'	System	08 Feb 2021 20:11:54

US3662023

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:34
User entered '1'	System	08 Feb 2021 20:11:54
DataPoint set to visible.	System	08 Feb 2021 20:11:54

US3662023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:12:13

US3662023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Feb 2021'	Angela Snyder (b) (4)	08 Feb 2021 20:12:13

US3662023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[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 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	08 Feb 2021 20:12:13

US3662023

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'OLD29'	System	08 Feb 2021 20:12:13

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User accepted default value 'Pre-Dose (PREDOSE)'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Feb 2021'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '08:15'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered '5 Feb 2021 08:15'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '97.8' F	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'infrared thermometer'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '51'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'bpm'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '12'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'breaths/min'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '117'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'mmHg'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '65'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'mmHg'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User accepted default value 'Post-Dose (POSTDOSE)'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Feb 2021'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '09:34'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered '5 Feb 2021 09:34'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '97.7' F	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Other (Other)'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'infrared thermometer'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '54'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'bpm'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '16'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'breaths/min'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '107'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'mmHg'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '64'	Angela Snyder (b) (4)	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'mmHg'	System	08 Feb 2021 20:13:58

US3662023

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:14:09

US3662023

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Feb 2021'	Angela Snyder (b) (4)	08 Feb 2021 20:14:09

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

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 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'mRNA-1273'	System	08 Feb 2021 20:14:39
DataPoint set to visible.	System	08 Feb 2021 20:11:54

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '5 Feb 2021'	Angela Snyder (b) (4)	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '09:04'	Angela Snyder (b) (4)	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered '5 Feb 2021 09:04'	System	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Left Arm (LEFT ARM)'	Angela Snyder (b) (4)	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'ONCE'	System	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 20:14:39

US3662023

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:14:45

US3662023

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:44
User entered 'I'	System	08 Feb 2021 20:14:45

US3662023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	12 Feb 2021 14:10:14

US3662023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered '12 Feb 2021'	Angela Snyder (b) (4)	12 Feb 2021 14:10:14

US3662023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	12 Feb 2021 14:10:14

US3662023

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered empty.	Angela Snyder (b) (4)	12 Feb 2021 14:10:14

US3662023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)'	Angela Snyder (b) (4)	12 Feb 2021 14:10:18

US3662023

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:02
User entered '1'	System	12 Feb 2021 14:10:18

US3662023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Mar 2021 14:54:59

US3662023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '5 Mar 2021'	Angela Snyder (b) (4)	05 Mar 2021 14:54:59

US3662023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[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 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	05 Mar 2021 14:54:59

US3662023

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User entered 'OLD57'	System	05 Mar 2021 14:54:59

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '5 Mar 2021'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '08:09'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User entered '5 Mar 2021 08:09'	System	05 Mar 2021 14:56:01

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '97.8' F	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'Other (Other)'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'infrared thermometer'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '56'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User entered 'bpm'	System	05 Mar 2021 14:56:01

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '16'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User entered 'breaths/min'	System	05 Mar 2021 14:56:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '115'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User entered 'mmHg'	System	05 Mar 2021 14:56:01

US3662023

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '74'	Angela Snyder (b) (4)	05 Mar 2021 14:56:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User entered 'mmHg'	System	05 Mar 2021 14:56:01

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'No (N)'	Angela Snyder (b) (4)	05 Mar 2021 14:56:10

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered empty.	Angela Snyder (b) (4)	05 Mar 2021 14:56:10

US3662023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Mar 2021 14:56:31

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '5 Mar 2021'	Angela Snyder (b) (4)	05 Mar 2021 14:56:31

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '08:16'	Angela Snyder (b) (4)	05 Mar 2021 14:56:31

US3662023

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:45
User entered '5 Mar 2021 08:16'	System	05 Mar 2021 14:56:31

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 23:00:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 7 - 22Sep2020; end date: Day 9 - 24Sep2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:56:11
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 7 - 22Sep2020; end date: Day 9 - 24Sep2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'no redness reported in ed diary 1 however, injection site pain was recorded. Added to AE log. ' (Site from DM).	michelle saemann (b) (4) (b) (4)	08 Feb 2021 21:36:17
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE REDNESS persist beyond Day 7 (start date: Day 7 - 22Sep2020; end date: Day 9 - 24Sep2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 18:52:41
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:27:24
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:58:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 15:58:13
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:55:45
User entered		
'USA-US088-2021-mRNA-1273-P301000003'	System	11 Jan 2021 20:55:36
User entered 'New'	(b) (4), (b) (6)	11 Jan 2021 20:55:36

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 15:58:13
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 17:41:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Jan 2021 17:41:39
Data point term sent to Coder	System	11 Jan 2021 17:40:42
User entered 'symptomatic covid-19'	Angela Snyder (b) (4)	11 Jan 2021 17:40:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '7 Jan 2021'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:55:34
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'PV Query: End date provided as 15 Jan 2021, but symptoms were still reported on that date. Please update the end date, or confirm that this is correct.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 20:15:19
Query 'PV Query: End date provided as 15 Jan 2021, but symptoms were still reported on that date. Please update the end date, or confirm that this is correct.' answered with 'updated' (Site from Safety).	MaKayla Bishop (b) (4) (b) (4)	12 Feb 2021 16:49:58
DataPoint Un-verified.	MaKayla Bishop (b) (4) (b) (4)	12 Feb 2021 16:49:49
User entered '16 Jan 2021' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	12 Feb 2021 16:49:49
User opened query 'PV Query: End date provided as 15 Jan 2021, but symptoms were still reported on that date. Please update the end date, or confirm that this is correct.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:17:37
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. (did not issue as answered in RAVE)' canceled (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:16:55
User opened 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. (did not issue as answered in RAVE)' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:16:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:20:48
User closed query 'Per source end date is 17Jan2021. Please verify and update as needed.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 18:27:33
Query 'Per source end date is 17Jan2021. Please verify and update as needed.' answered with 'source updated' (Site from CRA).	michelle saemann (b) (4) (b) (4)	01 Feb 2021 17:49:44
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:19
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per source end date is 17Jan2021. Please verify and update as needed. ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 15:53:47
User entered '15 Jan 2021' reason for change: Data Entry Error	michelle saemann (b) (4)	21 Jan 2021 20:04:39
User entered '17 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	19 Jan 2021 16:55:34
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	11 Jan 2021 17:40:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4)	11 Jan 2021 17:40:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4)	11 Jan 2021 17:40:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4)	11 Jan 2021 17:40:33
	(b) (4)	

US3662023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'None (NONE)' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	20 Jan 2021 18:22:33
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	25 Feb 2021 18:46:04
	MaKayla Bishop (b) (4)	25 Feb 2021 18:46:04
	(b) (4)	
User entered '1' reason for change: Data Entry Error	MaKayla Bishop (b) (4)	25 Feb 2021 18:46:04
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Feb 2021 15:13:27
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0' reason for change: Data Entry Error	Angela Snyder (b) (4)	28 Jan 2021 12:54:59
	(b) (4)	
User entered '1'	Angela Snyder (b) (4)	11 Jan 2021 17:40:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:16:45
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'no medication taken, updated.' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	25 Feb 2021 18:46:28
DataPoint Un-verified.	MaKayla Bishop (b) (4)	25 Feb 2021 15:13:27
User entered '0' reason for change: Data Entry Error	(b) (4) MaKayla Bishop (b) (4)	25 Feb 2021 15:13:27
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 03:33:55
Query 'Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:17:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 16:14:42
User entered '1' reason for change: Data Entry Error	Angela Snyder (b) (4)	28 Jan 2021 15:58:13
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 12:54:59
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Participant did not take anything for COVID. He did take tylenol for HA, related to COVID, should I capture that here?' (Site from Safety).	(b) (4)	22 Jan 2021 18:33:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 20:06:29
User entered '0'	Angela Snyder (b) (4)	20 Jan 2021 20:52:02
	(b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
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. (did not issue as answered in RAVE)' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:17:07
User opened 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. (did not issue as answered in RAVE)' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:16:05
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:55:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Jan 2021 17:40:33

US3662023

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 23:00:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Jan 2021 17:40:33

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: Appetite disorders, PT: Decreased appetite, LLT: Decreased appetite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 17:43:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 17:43:39
Data point term sent to Coder	System	11 Jan 2021 17:42:43
User entered 'decreased appetite'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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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)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '25 Dec 2020'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User entered empty.	System	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:56:05
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '17 Jan 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Jan 2021 16:56:05
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User entered empty.	System	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Form: Adverse Events (4)

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[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'l'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:56:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (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)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:58:13
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User entered '0'	System	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58
User entered '0'	System	11 Jan 2021 17:41:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 23:00:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:48:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 12:20:35

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\23.0.	Coder Import (b) (4)	19 Feb 2021 01:16:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Feb 2021 01:16:00
Data point term sent to Coder	System	08 Feb 2021 21:34:12
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 21:33:43
User entered 'pain at injection site, ipsilateral to study med injection' reason for change: Data Entry Error	michelle saemann (b) (4)	08 Feb 2021 21:33:43
Data point term sent to Coder	System	08 Feb 2021 21:32:11
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
Data point term sent to Coder	System	19 Jan 2021 16:50:43
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 16:50:20
User entered empty; reason for change Data Entry Error	michelle saemann (b) (4)	19 Jan 2021 16:50:20
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 13:38:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Jan 2021 13:38:56
Data point term sent to Coder	System	15 Jan 2021 13:37:58
User entered 'chills'	Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'PV Query: Since an event of Covid-19 has been reported, and this is a symptom of Covid and not the diagnosis itself, please update answer to 'No'. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 15:17:46
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	michelle saemann (b) (4)	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 16:50:20
User entered empty; reason for change Data Entry Error	michelle saemann (b) (4)	19 Jan 2021 16:50:20
Query 'PV Query: Since an event of Covid-19 has been reported, and this is a symptom of Covid and not the diagnosis itself, please update answer to 'No'. ' answered with 'Data updated' (Site from Safety).	Angela Snyder (b) (4)	19 Jan 2021 16:49:29
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	19 Jan 2021 16:49:13
User opened query 'PV Query: Since an event of Covid-19 has been reported, and this is a symptom of Covid and not the diagnosis itself, please update answer to 'No'. ' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 12:20:30
User entered 'Yes (Y)'	Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 21:33:43
User entered '22 Sep 2020' reason for change: Data Entry Error	michelle saemann (b) (4)	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 16:50:20
User entered empty; reason for change Data Entry Error	michelle saemann (b) (4)	19 Jan 2021 16:50:20
User entered '11 Jan 2021'	Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	System	15 Jan 2021 13:37:43

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
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	08 Feb 2021 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	System	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	System	08 Feb 2021 21:33:43
DataPoint inactivated with code reason code Data not required.	System	08 Feb 2021 21:31:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 21:31:11
User entered empty; reason for change Data Entry Error	System	08 Feb 2021 21:31:11
User entered 'No (N)'	System	08 Feb 2021 21:31:11

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Form: Adverse Events (5)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '24 Sep 2020' reason for change: Data Entry Error	michelle saemann (b) (4)	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty; reason for change Data Entry Error	michelle saemann (b) (4)	19 Jan 2021 16:50:20
User entered '12 Jan 2021'	Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
DataPoint activated with code reason code Data required.	Michelle Saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	Michelle Saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	System	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
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	08 Feb 2021 21:33:43
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	System	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:33:43
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	michelle saemann (b) (4)	08 Feb 2021 21:31:11
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	michelle saemann (b) (4)	19 Jan 2021 16:50:36
	(b) (4)	
	System	19 Jan 2021 16:50:20
	michelle saemann (b) (4)	19 Jan 2021 16:50:20
	(b) (4)	
	Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
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	08 Feb 2021 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	System	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	System	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	System	19 Jan 2021 16:50:36
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Jan 2021 16:50:20
User entered empty; reason for change Data Entry Error	System	19 Jan 2021 16:50:20
User entered 'No (N)'	Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	(b) (4)	
	Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

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Form: Adverse Events (5)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Form: Adverse Events (5)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

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Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

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Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 21:33:43
User entered 'Related (RELATED)' reason for change: Data Entry Error	michelle saemann (b) (4)	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	(b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 16:50:36
User entered empty; reason for change Data Entry Error	System	19 Jan 2021 16:50:20
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4)	19 Jan 2021 16:50:20
	(b) (4)	
	Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
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	08 Feb 2021 21:33:43
User entered 'Related (RELATED)' reason for change: Data Entry Error	System	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:33:43
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	michelle saemann (b) (4)	08 Feb 2021 21:31:11
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4)	19 Jan 2021 16:50:36
	(b) (4)	
	System	19 Jan 2021 16:50:20
	michelle saemann (b) (4)	19 Jan 2021 16:50:20
	(b) (4)	
	Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
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	08 Feb 2021 21:33:43
User entered 'None (NONE)' reason for change: Data Entry Error	System	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:33:43
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	michelle saemann (b) (4)	08 Feb 2021 21:31:11
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	michelle saemann (b) (4)	19 Jan 2021 16:50:36
	(b) (4)	
	System	19 Jan 2021 16:50:20
	michelle saemann (b) (4)	19 Jan 2021 16:50:20
	(b) (4)	
	Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	08 Feb 2021 21:33:43
DataPoint activated with code reason code Data required.	System	
DataPoint inactivated with code reason code Data not required.	System	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Jan 2021 16:50:20
User entered '0' reason for change: Data Entry Error	System	
User entered '1'	System	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

US3662023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

US3662023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 21:33:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	michelle saemann (b) (4)	08 Feb 2021 21:33:43
Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	System	19 Jan 2021 16:50:20
	michelle saemann (b) (4)	19 Jan 2021 16:50:20
	(b) (4)	
	Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43

US3662023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
DataPoint activated with code reason code Data required.	(b) (4) michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered empty.	(b) (4) Angela Snyder (b) (4)	15 Jan 2021 13:37:43
	(b) (4)	

US3662023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User entered '0'	michelle saemann (b) (4)	19 Jan 2021 16:50:36
	(b) (4)	
	System	15 Jan 2021 13:37:43

US3662023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36
User entered '0'	System	15 Jan 2021 13:37:43

US3662023

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:14
DataPoint activated with code reason code Data required.	michelle saemann (b) (4)	08 Feb 2021 21:31:11
DataPoint inactivated with code reason code Data not required.	michelle saemann (b) (4)	19 Jan 2021 16:50:36

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:00:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:05:18

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Sep 2020 17:08:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:08:32
Data point term sent to Coder	System	25 Sep 2020 16:55:33
User entered 'OMEPRAZOLE'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'No (N)'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'HEARTBURN'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered '20'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'mg (mg)'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'once daily (QD)'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered '11 Aug 2020'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	05 Jan 2021 17:03:41
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	05 Jan 2021 17:03:41
User entered empty.	(b) (4)	
	Brenda Miller (b) (4)	25 Sep 2020 16:55:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'No (N)'	Brenda Miller (b) (4)	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User entered '1'	System	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User entered '1'	System	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:24
User entered '804 (804)'	System	25 Sep 2020 16:55:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Sep 2020 17:08:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:08:34
Data point term sent to Coder	System	25 Sep 2020 16:56:34
User entered 'GABAPENTIN'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:56:23

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'ANXIETY'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:56:23

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '300'	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:56:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'three times daily (TID)'	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '15 Feb 2020'	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:56:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Sep 2020 16:56:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:56:23

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 16:56:23

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Sep 2020 17:08:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:08:40
Data point term sent to Coder	System	25 Sep 2020 16:57:34
User entered 'LAMOTRIGINE'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:57:07

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'BIPOLAR'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:57:07

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered '200'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:57:07

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:57:07

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '15 Feb 2020'	Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:57:07
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:57:07

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:57:07

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 16:57:07

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Sep 2020 17:08:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:08:45
Data point term sent to Coder	System	25 Sep 2020 16:58:35
User entered 'LISINOPRIL'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:57:46

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'HYPERTENSION'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '10'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:57:46

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '15 Jul 2016'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	25 Sep 2020 16:57:46
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:57:46

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:57:46

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 16:57:46

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 09:03:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 09:03:44
Data point term sent to Coder	System	25 Sep 2020 16:58:38
User entered 'TRAZODONE HCI'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:58:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'INSOMNIA'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:58:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '50'	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:58:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:58:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '15 Jul 2016'	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:58:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	25 Sep 2020 16:58:20
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:58:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:58:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 16:58:20

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Dec 2020 20:42:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Dec 2020 20:42:46
Data point term sent to Coder Coding entries removed.	System MaKayla Bishop (b) (4)	03 Dec 2020 20:42:20 03 Dec 2020 20:42:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:08:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 17:08:49
Data point term sent to Coder User entered 'ASPIRIN'	System Brenda Miller (b) (4)	25 Sep 2020 16:59:39 25 Sep 2020 16:59:10

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. PROPHYLAXIS FOR [Medical Condition/Diagnosis]). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 06:42:23
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. PROPHYLAXIS FOR [Medical Condition/Diagnosis]). Update Con Med eCRF as appropriate. ' answered with 'PRIMARY PREVENTION ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	03 Dec 2020 20:47:04
User entered 'HEART HEALTH' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	03 Dec 2020 20:42:10
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. PROPHYLAXIS FOR [Medical Condition/Diagnosis]). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:24:23
User entered 'PROPHYLACTIC'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:59:10

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '81'	Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:59:10

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered empty.	(b) (4) Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '15 Jul 2002'	Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:59:10

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	25 Sep 2020 16:59:10
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4) (b) (4)	25 Sep 2020 16:59:10

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:59:10

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 16:59:10

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 16:59:10

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
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.	(b) (4) Coder Import (b) (4)	05 Jan 2021 17:07:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 17:07:37
Data point term sent to Coder	System	05 Jan 2021 17:05:41
User entered 'famotidine'	Angela Snyder (b) (4) (b) (4)	05 Jan 2021 17:04:42

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'heartburn'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '10'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'twice daily (BID)'	(b) (4) Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '1 Nov 2020'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	05 Jan 2021 17:04:42
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Jan 2021 17:04:42

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 17:04:42

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Jan 2021 17:04:42

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
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)	13 Jan 2021 13:56:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 13:56:59
Data point term sent to Coder	System	13 Jan 2021 13:55:26
User entered 'Tylenol'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User closed query 'Per ETRTR: According to relationship with COVID-19 AE, please consider to tick on "Concomitant Medications" action taken within COVID-19 AE, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 16:05:40
Query 'Per ETRTR: According to relationship with COVID-19 AE, please consider to tick on "Concomitant Medications" action taken within COVID-19 AE, thanks.' answered with 'Data updated' (Site from CRA).	Angela Snyder (b) (4) (b) (4)	28 Jan 2021 12:54:39
User opened query 'Per ETRTR: According to relationship with COVID-19 AE, please consider to tick on "Concomitant Medications" action taken within COVID-19 AE, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 18:23:13
User entered 'headache'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered '1000'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered empty.	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered empty.	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered empty.	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered '12 Jan 2021'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered '0'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered '12 Jan 2021'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:06:38
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User entered empty.	System	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User entered empty.	System	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:20
User entered empty.	System	13 Jan 2021 13:55:17

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: CAPSAICIN AND SIMILAR AGENTS, PRODUCT: CAPSAICIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:50:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 07:50:48
Data point term sent to Coder	System	15 Mar 2021 17:44:33
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	15 Mar 2021 17:44:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	22 Feb 2021 14:54:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: CAPSAICIN AND SIMILAR AGENTS, PRODUCT: CAPSAICIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:40:39
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 Feb 2021 00:40:39
Data point term sent to Coder	System	08 Feb 2021 20:20:59
User entered 'capsaicin 0.1%'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:20:39

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:23
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' answered with 'SOURCES UPDATED. ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	15 Mar 2021 17:44:42
Signature has been broken.	MaKayla Bishop (b) (4) (b) (4)	15 Mar 2021 17:44:31
User entered 'ARTHRITIS, BACK PAIN, OSTEOARTHRITIS' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	15 Mar 2021 17:44:31
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:07:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	22 Feb 2021 14:54:36
User entered 'arthritis, back pain'	Angela Snyder (b) (4) (b) (4)	08 Feb 2021 20:20:39

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '1'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Application'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'as needed (PRN)'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Topical (TOPICAL)'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med CAPSAICIN was added/changed on 26 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: Con Med CAPSAICIN was added/changed on 26 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'no change in grade, not worsening. Pt. wanted to see if cream would help. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 03:33:14
User opened query 'Per DM CLR: Con Med CAPSAICIN was added/changed on 26 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). User signature succeeded.	michelle saemann (b) (4)	15 Mar 2021 17:48:12
User entered '26 Jan 2021'	(b) (4), (b) (6)	11 Mar 2021 12:07:21
	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	Angela Snyder (b) (4)	08 Feb 2021 20:20:39

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:36
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Feb 2021 20:20:39
	(b) (4)	

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 20:20:39

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 20:20:39

US3662023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Feb 2021 20:20:39

US3662023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:00:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Feb 2021 20:20:59
User entered 'No (N)'	(b) (4)	
	Brenda Miller (b) (4)	25 Sep 2020 16:59:30
	(b) (4)	

US3662023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 23:00:46

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
User entered '8 Feb 2021'	Angela Snyder (b) (4)	08 Feb 2021 20:21:23
	(b) (4)	

US3662023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 23:00:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
User entered 'abnormal ultrasound'	Angela Snyder (b) (4)	08 Feb 2021 20:21:23
	(b) (4)	

US3662023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 23:00:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Angela Snyder (b) (4)	08 Feb 2021 20:21:23
	(b) (4)	

US3662023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 23:00:46

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Feb 2021 20:21:23
	(b) (4)	

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'USA-US088-2021-MRNA-1273-P301000003'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Carl'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Fichtenbaum'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered '231 Albert Sabin Way'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Cincinnati'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered '45267'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 18:33:41
User entered 'US'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Mar 2021 20:16:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
User entered '2'	System	22 Jan 2021 18:33:51
User entered '1'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'USA-US088-2021-MRNA-1273-P301000003'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Carl'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Fichtenbaum'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered '231 Albert Sabin Way'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Cincinnati'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered '45267'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 18:33:41
User entered 'US'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Mar 2021 20:16:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
User entered '2'	System	22 Jan 2021 18:33:51
User entered '1'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:00:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
User entered '11/Jan/2021 15:56'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:00:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 18:33:41
User entered 'I'	(b) (4), (b) (6)	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'USA-US088-2021-MRNA-1273-P301000003'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Carl'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Fichtenbaum'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered '231 Albert Sabin Way'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Cincinnati'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered '45267'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 18:33:41
User entered 'US'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Mar 2021 20:16:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
User entered '2'	System	22 Jan 2021 18:33:51
User entered '1'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 23:00:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
User entered '22/Jan/2021 13:33'	System	22 Jan 2021 18:33:51

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 23:00:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 20:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 18:33:51

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'USA-US088-2021-MRNA-1273-P301000003'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'No (N)'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Carl'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Fichtenbaum'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered '231 Albert Sabin Way'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered 'Cincinnati'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	11 Jan 2021 20:56:00
User entered '45267'	System	11 Jan 2021 20:55:36

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:04:46
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 18:33:41
User entered 'US'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 23:00:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Mar 2021 20:16:18
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:54:47
	(b) (4)	
User entered '2'	System	22 Jan 2021 18:33:51
User entered '1'	System	11 Jan 2021 20:56:10

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 23:00:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:07:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered '15/Mar/2021 16:16'	(b) (4) System	15 Mar 2021 20:16:18

US3662023

Folder: SAE USA-US088-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 23:00:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:07:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:17:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 20:16:18