

US3662032 (Prod: Cincinnati CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:19:44

All time stamps listed in this document are displayed in GMT

US3662032

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Participant ID

US3662032

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

US3662032

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
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

US3662032

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3662032

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Were any significant conditions reported?

Yes ☒

No ☐

US3662032

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Condition	HYPERTENSION NEC
Start date (dd MMM yyyy)	01 JUL 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3662032

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Condition	ANKLE SORENESS
Start date (dd MMM yyyy)	01 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)	_____

US3662032

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Condition	KNEE SORENESS
Start date (dd MMM yyyy)	01 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)	

US3662032

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Condition	OSTEOARTHRITIS OF LEFT HIP
Start date (dd MMM yyyy)	6 FEB 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3662032

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:38 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 08:38
Height (<i>xxx.x</i>)	173.5 cm
Weight (<i>xxx.x</i>)	107 kg
BMI (<i>xxx.x</i>)	35.54552 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662032

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:56:34

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3662032

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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	

US3662032

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

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

What was the participant's randomization number? 108265

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 ☒

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Height	ND - Not Done
Weight	ND - Not Done

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	08:38 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 08:38
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	176 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	111 mmHg
Diastolic Blood Pressure units	MMHG

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 10:28
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	173 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	121 mmHg
Diastolic Blood Pressure units	MMHG

US3662032

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

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.

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

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) 01 SEP 2020

What was the treatment time? (00:00-23:59) 09:58 (24 HR)

Treatment Date and Time (derived) 01 SEP 2020 09:58

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

US3662032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 SEP 2020
Collection time (00:00-23:59)	08:15 (24 HR)
Collection date and time (derived)	01 SEP 2020 08:15

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:35	01 SEP 2020 08:35
Nasopharyngeal Swab 2	No		

US3662032

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 10:21

PC Open Date & Time

01 SEP 2020 10:18

PC Close Date & Time

01 SEP 2020 12:48

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp	01 SEP 2020 13:45
PC Open Date & Time	01 SEP 2020 13:43
PC Close Date & Time	02 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:00

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 15:12

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 09:35

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 08:05

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 10:21

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 10:22

PC Open Date & Time

01 SEP 2020 10:18

PC Close Date & Time

01 SEP 2020 12:48

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:44

PC Open Date & Time

01 SEP 2020 13:43

PC Close Date & Time

02 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 12:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 12:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 15:12

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

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

06 SEP 2020 09:35

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

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

07 SEP 2020 08:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

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

08 SEP 2020 10:21

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 10:23
PC Open Date & Time	01 SEP 2020 10:18
PC Close Date & Time	01 SEP 2020 12:48

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 13:44
PC Open Date & Time	01 SEP 2020 13:43
PC Close Date & Time	02 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

45 of 3584

EAB) (1725)

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

47 of 3584

EAB) (1725)

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:01
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

49 of 3584

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 15:12
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 3584

EAB) (1725)

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 09:36
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3584

EAB) (1725)

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 08:06
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

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 ☒

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 10:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3662032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	08:11 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 08:11
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 09:45
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

US3662032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:15 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 09:15

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

US3662032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

09:05 (24 HR)

Collection date and time (derived)

29 SEP 2020 09:05

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:00	29 SEP 2020 09:00
Nasopharyngeal Swab 2	No		

US3662032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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

29 SEP 2020 09:36

PC Open Date & Time

29 SEP 2020 09:35

PC Close Date & Time

29 SEP 2020 12:05

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	30 SEP 2020 07:02
PC Open Date & Time	29 SEP 2020 13:00
PC Close Date & Time	30 SEP 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

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

97.1 °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

01 OCT 2020 06:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 05:59

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 03:38

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

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

04 OCT 2020 05:59

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 05:55

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

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

06 OCT 2020 07:14

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 09:37

PC Open Date & Time

29 SEP 2020 09:35

PC Close Date & Time

29 SEP 2020 12:05

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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

30 SEP 2020 07:03

PC Open Date & Time

29 SEP 2020 13:00

PC Close Date & Time

30 SEP 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

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

01 OCT 2020 06:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

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

02 OCT 2020 06:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

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

03 OCT 2020 03:38

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

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

04 OCT 2020 06:00

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 05:56

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

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

06 OCT 2020 07:14

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 09:38
PC Open Date & Time	29 SEP 2020 09:35
PC Close Date & Time	29 SEP 2020 12:05

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 07:03
PC Open Date & Time	29 SEP 2020 13:00
PC Close Date & Time	30 SEP 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

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 ☒

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 06:02
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

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 ☒

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 06:00
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 3584

EAB) (1725)

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 03:38
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

97 of 3584

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 06:00
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

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 ☒

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 05:56
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

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 ☒

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 07:15
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3662032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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

PARTICIPANT IS OUT OF THE
COUNTRY. TEXTED
PARTICIPANT ON NUMEROUS
TIMES AND GOT NO RESPONSE

US3662032

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	08:10 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 08:10
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

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.

US3662032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	08:15 (24 HR)
Collection date and time (derived)	27 OCT 2020 08:15

US3662032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:35

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 17:59:24
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 13:29:56

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 17:59:18

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 <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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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	03 DEC 2020 01:55:07
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 17:59:19

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 12:00:23

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 04:24:13

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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	31 DEC 2020 01:17:54
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

07 JAN 2021 00:10:31

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

14 JAN 2021 00:03:53

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 12:00:34

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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	28 JAN 2021 05:58:51
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

06 FEB 2021 12:00:25

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 02:05:32

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 07:06:01

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 FEB 2021 12:06:20
Patient Cloud Open Date & Time	25 FEB 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
133 of 3584	

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 MAR 2021 07:58:51
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 MAR 2021 18:01:51
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 11:07:36

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 21:02:12

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 12:30:51
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 APR 2021 12:09:09
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 12:29:20

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 12:28:44

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 MAY 2021 12:28:32
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 <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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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°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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Patient Cloud Open Date & Time	11 NOV 2021 00:01
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Patient Cloud Close Date & Time	15 NOV 2021 23:59
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US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Patient Cloud Open Date & Time	25 NOV 2021 00:01
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Patient Cloud Close Date & Time	29 NOV 2021 23:59
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US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 <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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 <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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐ 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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Patient Cloud Open Date & Time	11 AUG 2022 00:01
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Patient Cloud Close Date & Time	15 AUG 2022 23:59
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US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Patient Cloud Open Date & Time	18 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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="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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Date and time of submission

Patient Cloud Open Date & Time	27 OCT 2022 00:01
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Patient Cloud Close Date & Time	31 OCT 2022 23:59
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US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3662032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:19:44

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 07:58:13

US3662032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 MAR 2021
Time of assessment (00:00-23:59)	07:09 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 07:09
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 MAR 2021

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

US3662032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	07:16 (24 HR)
Collection date and time (derived)	18 MAR 2021 07:16

US3662032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:39:07

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:39:07

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Date of Contact	24 FEB 2021
Time of Contact	09:18
Date and Time of Contact (derived)	24 FEB 2021 09:18
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input 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>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

322 of 3584

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

	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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

326 of 3584

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

	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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

330 of 3584

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

	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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

334 of 3584

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

	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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" 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)

338 of 3584

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

339 of 3584

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 FEB 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.0 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 type="checkbox"/>
	Mild	<input checked="" 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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

	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"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Date of Visit	24 FEB 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	24 FEB 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)	0

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Date of Contact	24 FEB 2021
Time of Contact	09:18
Date and Time of Contact (derived)	24 FEB 2021 09:18
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input 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>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input 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"/>
Day 33	<input type="checkbox"/>

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

	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	
Assessment Not Done	
O2 Saturation	
O2 Saturation Units	
Temperature	

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

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

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

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Fatigue	None	<input type="checkbox"/>
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US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Date of Visit	24 FEB 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	24 FEB 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
CLIA Certified?	Yes <input checked="" type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

Visit date (dd MMM yyyy)	24 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:34
Height (xxx.x)	173 cm
Weight (xxx.x)	105.23 kg
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3662032

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

24 FEB 2021

US3662032

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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

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

Folder OID	UNBLND_DECIDE
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US3662032

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 19:02:44

Generated On: 10 Jun 2021 09:19:44

Date of updated informed consent (<i>dd MMM yyyy</i>)	11 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	11 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3662032

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Height	173 cm
Weight	105.2 kg
BMI (xxx.x)	35.14985

US3662032

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Height	173 cm
Weight	105.2 kg
BMI (xxx.x)	35.14985
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	07:15 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 07:15
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3662032

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Height	173 cm
Weight	105.2 kg
BMI (xxx.x)	35.14985
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	08:22 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 08:22
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3662032

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3662032

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 07:52 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 07:52

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

US3662032

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	07:40 (24 HR)
Collection date and time (derived)	11 JAN 2021 07:40

US3662032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	07:35
Collection Date and Time (derived)	11 JAN 2021 07:35

US3662032

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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)	18 FEB 2021
Time of assessment (00:00-23:59)	07:13 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 07:13
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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)	18 FEB 2021
Time of assessment (00:00-23:59)	08:42 (24 HR)
Vital Signs Date and Time (derived)	18 FEB 2021 08:42
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3662032

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3662032

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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) 18 FEB 2021

What was the treatment time? (00:00-23:59) 08:12 (24 HR)

Treatment Date and Time (derived) 18 FEB 2021 08:12

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

US3662032

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:18:01

Generated On: 10 Jun 2021 09:19:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662032

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 MAR 2021
Time of assessment (00:00-23:59)	07:09 (24 HR)
Vital Signs Date and Time (derived)	18 MAR 2021 07:09
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662032

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 MAR 2021

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

US3662032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	07:16 (24 HR)
Collection date and time (derived)	18 MAR 2021 07:16

US3662032

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Mar 2021 21:18:00

Generated On: 10 Jun 2021 09:19:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

AEID

Adverse event

ERYTHEMA PRESENT IN
BILATERAL EXTERNAL EAR
CANALS. NO EXUDATE, NON
URTICARIAL

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)

24 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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 ☐

PRODUCTION RELEASE (v12.003

383 of 3584

EAB) (1725)

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

AEID	
Adverse event	NOSE BLEED IN RIGHT NOSTRIL
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 FEB 2021
Start time (00:00-23:59)	22:00 (24 HR)
AE start date and time (derived)	19 FEB 2021 22:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 FEB 2021
End time (00:00-23:59)	18:00 (24 HR)
AE End Date and Time (derived)	24 FEB 2021 18:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 3584

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

AEID

Adverse event

COMMUNITY ACQUIRED
PNEUMONIA OF RIGHT LOWER
LOBE OF LUNG

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)

26 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

5 MAR 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

PRODUCTION RELEASE (v12.003

387 of 3584

EAB) (1725)

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

AEID

Adverse event

ENTEROVIRUS HUMAN
RHINOVIRUS INFECTION,
UNSPECIFIED

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)

24 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

27 FEB 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

PRODUCTION RELEASE (v12.003

389 of 3584

EAB) (1725)

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

AEID	
Adverse event	WORSENING OSTEOARTHRITIS OF LEFT HIP (INCREASE FROM GRADE 2)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	3 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	
391 of 3584	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

AEID

Adverse event

LEFT HIP PAIN, S/P HIP
REPLACEMENT

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)

5 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 3584

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

AEID	
Adverse event	NOSE BLEEDS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 3584

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

AEID

Adverse event

BRIGHT RED SANGUINEOUS
DRAINAGE FROM LEFT HIP
INCISION

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)

18 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

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

PRODUCTION RELEASE (v12.003

397 of 3584

EAB) (1725)

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

AEID	
Adverse event	PURE HYPERCHOLESTEROLEMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 3584

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

AEID	USA-US088-2021-MRNA-1273-P30 1000012
Adverse event	INFECTION/INFLAMMATION REACTION DUE TO INTERNAL LEFT HIP PROSTHESIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 APR 2021
Hospital Discharge Date (dd MMM yyyy)	13 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 3584

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

PARTICIPANT ADMITTED FOR
REVISED HIP JOINT
REPLACEMENT. WE ARE
WORKING ON OBTAINING
RECORDS. WILL UPDATE ONCE
MORE INFORMATION IS
OBTAINED.

4/21/21 PARTICIPANT HAD LEFT
HIP ARTHROPLASTY ON 3/5/21.
DEVELOPED BLOODY
DRAINAGE FROM THE
INCISION AROUND POST OP
WEEK 3. ON 4/7/21 POST OP F/U
VISIT HE REPORTED
CONTINUED DRAINAGE.
SMALL PART OF INCISION WAS
OPENED WITH HEMOSTATS
AND COULD BE PROBED
2-2.5CM. AFTER EXAM, IT WAS
DECIDED THAT PARTICIPANT
WOULD BE SCHEDULED FOR A
POST LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE.
PROCEDURE DONE ON 4/8/21.
CULTURES REVEALED MRSA
AND PSEUDOMONAS. AT
DISCHARGE, PT. SENT HOME
ON IV ABT.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

AEID

Adverse event

DRAINING HEMATOMA,
STATUS POST LEFT TOTAL HIP
ARTHROPLASTY

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)

8 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

8 APR 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

PRODUCTION RELEASE (v12.003

404 of 3584

EAB) (1725)

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 14:56:34

Generated On: 10 Jun 2021 09:19:44

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

Yes ☒

No ☐

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

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ANKLE/KNEES SORENESS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

407 of 3584

EAB) (1725)

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication MULTIVITAMINS

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

409 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration .2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

411 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUL 2006
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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)

413 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2006	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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)

415 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUL 2006	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication (J18.9) COMMUNITY ACQUIRED
PNEUMONIA OF RIGHT LOWER
LOBE OF LUNG

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

417 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication (J18.9) COMMUNITY ACQUIRED
PNEUMONIA OF RIGHT LOWER
LOBE OF LUNG

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

419 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication COMMUNITY ACQUIRED
PNEUMONIA OF RIGHT LOWER
LOBE OF LUNG

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

421 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication CEFPODOXIME PROXETIL

Prophylaxis Yes ☐
No ☒

Indication COMMUNITY ACQUIRED
PNEUMONIA OF RIGHT LOWER
LOBE OF LUNG

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

423 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 2021
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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)

425 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNK	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP PAIN, S/P LEFT TOTAL
HIP ARTHROPLASTY

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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)

427 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication TRANEXAMIC ACID

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

429 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	ROUTE IS INFILTRATE	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication TOBRAMYCIN 1.2G

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

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)

431 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)		5 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication RIVAROXABAN

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL PROPHYLAXIS
LEFT TOTAL HIP
ARTHROPLASTY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

433 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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)

435 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNK	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication MIDAZOLAM HCL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNK

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

If dose unit is Other, specify UNK/UNKOWN

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)

437 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

439 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 MAR 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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication MELOXICAM; MOBIC

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP PAIN, S/P LEFT HIP
ARTHROPLASTY

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

441 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication	LACTATED RINGERS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LEFT TOTAL HIP ARTHROPLASTY
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNK/UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

443 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication LABETALOL HCL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNK

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

If dose unit is Other, specify UNK/UNKNOWN

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)

445 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication KETOROLAC TROMETHAMINE

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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)

447 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNK	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication HYDROMORPHONE HCL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 ☐

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication HYDRALAZINE HCL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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)

451 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNK	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP PAIN, S/P LEFT TOTAL
HIP ARTHROPLASTY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

453 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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)

455 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNK	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL PROPHYLAXIS
LEFT TOTAL HIP
ARTHROPLASTY

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

457 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 MAR 2021
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL PROPHYLAXIS
LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

459 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 MAR 2021
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration UNK

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

If dose unit is Other, specify UNK

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)

461 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNK	
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	5 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

463 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 MAR 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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL PROPHYLAXIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

465 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 MAR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication ACETAMINOPHEN; COMB;
HYDROCODONE BITARTRATE

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP PAIN S/P LEFT TOTAL
HIP ARTHROPLASTY

Dose per administration 325/5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

467 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	5 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

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)

469 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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)

471 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication VANCOMYCIN HCL

Prophylaxis Yes ☐
No ☒

Indication INFECTION/INFLAMMATION
REACTION DUE TO INTERNAL
LEFT HIP PROSTH, INIT (MRSA
AND PSEUDOMONAS)

Dose per administration 1.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

473 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication TOBRAMYCIN SULFATE

Prophylaxis Yes ☐
No ☒

Indication INFECTION/INFLAMMATION
REACTION DUE TO INTERNAL
LEFT HIP PROSTH, INIT (MRSA
AND PSEUDOMONAS)

Dose per administration 1.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

475 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		UNK
Start date (dd MMM yyyy)		8 APR 2021
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		8 APR 2021
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication SENNA CONCENTRATE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PREVENTION
POST SURGICAL PROCEDURE

Dose per administration 8.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

477 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	13 APR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication RIVAROXABAN

Prophylaxis Yes ☒
No ☐

Indication BLOOD CLOT PREVENTION
POST SURGICAL PROCEDURE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

479 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 APR 2021
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication LIDOCAINE PATCH 5%

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE

Dose per administration 1

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

If dose unit is Other, specify PATCH

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

481 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	13 APR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication SURGICAL PROCEDURE

Dose per administration 100

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)

483 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	10 APR 2021	
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"/>	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication DOCUSATE CALCIUM

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PREVENTION
POST SURGICAL PROCEDURE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

485 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication INFECTION/INFLAMMATION
REACTION DUE TO INTERNAL
LEFT HIP PROSTH, INIT (MRSA
AND PSEUDOMONAS)

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

487 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 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 APR 2021	
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"/>	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication ANTIBIOTIC CONTAINING
CALCIUM PHOSPHATE BEADS;
TOBRAMYCIN;VANCOMYCIN;G
ENTAMICIN

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP WOUND

Dose per administration 1.2/1/80

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

If dose unit is Other, specify MG/GM/MG

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

489 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	LEFT HIP WOUND	
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	8 APR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication VICODIN COMB;
ACETAMINOPHEN;HYDROCOD
ONE

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE

Dose per administration 325/5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

491 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 APR 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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

493 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	13 APR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication POST SURGICAL NAUSEA

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

495 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	9 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication CHLORHEXIDINE GLUCONATE

Prophylaxis Yes ☒
No ☐

Indication VENTILATOR ASSOCIATED
PNEUMONIA PREVENTION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

497 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	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)	9 APR 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 APR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication MELOXICAM; MOBIC

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

499 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 APR 2021	
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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY EVENING AT BEDTIME

Route of administration Oral ☒
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

501 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	17 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 APR 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"/>

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication CIPROFLOXACIN HCL

Prophylaxis Yes ☐
No ☒

Indication INFECTION/INFLAMMATION
DUE TO INTERNAL LEFT HIP
PROSTH, INIT (MRSA AND
PSEUDOMONAS)

Dose per administration 750

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

503 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

505 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	14 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 16 APR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY EVENING AT BEDTIME

Route of administration Oral ☒
Topical ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

507 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication BLOOD CLOT PREVENTION
POST SURGICAL PROCEDURE;
STATUS LEFT TOTAL HIP
ARTHROPLASTY REVISION
WITH INCISION AND
DEBRIDEMENT AND
POLYETHYLENE EXCHANGE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

509 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 13:39:06

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:47:46

Generated On: 10 Jun 2021 09:19:44

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 13:39:07

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 MAR 2021	LEFT HIP XRAY	Other	POST SURGICAL FOLLOW UP
5 MAR 2021	LEFT HIP AND PELVIS XRAY	Adverse Event	
5 MAR 2021	LEFT TOTAL HIP ARTHROPLASTY	Adverse Event	
5 MAR 2021	FLURO EXTREMITY SCAN OF LEFT HIP	Other	POST SURGERY PROCEDURE FOR CONFIRMATION
3 MAR 2021	KNEE BILATERAL 1 OR 2 VIEWS XRAY	Other	PRE OP PREVENTION SITE FRACTURE CARE PROTOCOL
6 NOV 2020	HIP BILATERAL 3 OR 4 VIEW XRAY	Medical History	
3 MAR 2021	CHEST 2 VIEW PA AND LAT XRAY	Adverse Event	
7 APR 2021	X-RAY LEFT HIP	Adverse Event	
8 APR 2021	REVISED HIP JOINT REPLACEMENT	Adverse Event	
8 APR 2021	HIP LT 3 OR 3 VW	Adverse Event	
8 APR 2021	LEFT HIP ARTHROPLASTY REVISION WITH INCISION AND DEBRIDEMENT AND POLYETHYLENE EXCHANGE	Adverse Event	
11 APR 2021	PICC LINE PLACEMENT CONFIRMED WITH CHEST X-RAY	Adverse Event	

US3662032

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:19:44

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

US3662032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:19:44

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 ☐

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 13:39:07

Generated On: 10 Jun 2021 09:19:44

SAEID	USA-US088-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input 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)	4

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 13:39:07

Generated On: 10 Jun 2021 09:19:44

SAEID	USA-US088-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input 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)	4
Date of submission (Pre-filled from custom function)	14/APR/2021 11:11
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

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 13:39:07

Generated On: 10 Jun 2021 09:19:44

SAEID	USA-US088-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input 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)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 08:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 13:39:07

Generated On: 10 Jun 2021 09:19:44

SAEID	USA-US088-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input 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)	4
Date of submission (Pre-filled from custom function)	21/APR/2021 13:06
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

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 13:39:07

Generated On: 10 Jun 2021 09:19:44

SAEID	USA-US088-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input 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)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 07:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3662032 (Prod: Cincinnati CRS)

US3662032

Form: Participant Creation

Generated On: 10 Jun 2021 09:19:44

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'US3662032'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:19:49

US3662032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:30:27

US3662032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:19:50

US3662032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:30:27

US3662032

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'SCRN'	System	01 Sep 2020 13:30:27

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered (b) (6) 1966'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:19:51

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '54'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'YEARS'	System	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered '54'	System	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Michelle Saemann (b) (4)	04 Sep 2020 22:01:07
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Michelle Saemann (b) (4)	04 Sep 2020 22:01:07
User entered '1'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty; reason for change Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	04 Sep 2020 22:01:07
User entered 'African American/African Heritage'	(b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:19:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:33:49

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'Sep 2020'	System	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered '2020'	System	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:19:50

US3662032

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:19:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'I'	System	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:19:44

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:21:33

US3662032

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:19:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	23 Sep 2020 16:01:02
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 13:35:49

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 16:02:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 16:02:35
Data point term sent to Coder	System	23 Sep 2020 16:02:06
User entered 'HYPERTENSION NEC'	Brenda Miller (b) (4)	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Jul 2006'	Brenda Miller (b) (4)	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'Jul 2006'	System	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered '2006'	System	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered empty.	System	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:19:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered empty.	System	23 Sep 2020 16:01:24

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Painful ankle - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Dec 2020 13:54:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 13:54:14
Data point term sent to Coder	System	09 Dec 2020 17:54:33
User entered 'ANKLE SORENESS'	Angela Snyder (b) (4) (b) (4)	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Jul 2018'	Angela Snyder (b) (4)	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Angela Snyder (b) (4)	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Angela Snyder (b) (4)	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Angela Snyder (b) (4)	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'Jul 2018'	System	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered '2018'	System	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered empty.	System	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:19:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered empty.	System	09 Dec 2020 17:54:30

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Dec 2020 17:55:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 17:55:55
Data point term sent to Coder	System	09 Dec 2020 17:55:34
User entered 'KNEE SORENESS'	Angela Snyder (b) (4) (b) (4)	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Jul 2018'	Angela Snyder (b) (4)	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Angela Snyder (b) (4)	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Angela Snyder (b) (4)	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Angela Snyder (b) (4)	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'Jul 2018'	System	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered '2018'	System	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered empty.	System	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:19:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered empty.	System	09 Dec 2020 17:55:03

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:36:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 18:05:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 18:05:32
Data point term sent to Coder	System	15 Mar 2021 18:05:03
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	michelle saemann (b) (4) (b) (4)	15 Mar 2021 18:04:37
' answered with 'updated' (Site from DM).		
Coding entries removed.	michelle saemann (b) (4) (b) (4)	15 Mar 2021 18:04:30
User entered 'osteoarthritis of left hip' reason for change: New Information	michelle saemann (b) (4) (b) (4)	15 Mar 2021 18:04:30
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:49:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:20:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:20:10

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	01 Mar 2021 16:51:56
User entered 'arthritis in hip'	Angela Snyder (b) (4)	01 Mar 2021 16:51:50
	(b) (4)	

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '6 Feb 2017'	Angela Snyder (b) (4)	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'Feb 2017'	System	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered '2017'	System	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered empty.	System	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:19:44

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered empty.	System	01 Mar 2021 16:51:50

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:38'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered '01 Sep 2020 08:38'	System	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '173.5' cm	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:37:36
DataPoint set to visible.	System	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '107' kg reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:42:15
User entered '235.8' kg	(b) (4), (b) (6)	01 Sep 2020 13:37:36
DataPoint set to visible.	System	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User closed query 'BMI \geq 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	System	01 Sep 2020 13:42:15
Query 'BMI \geq 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' answered by data change (Site from System).	System	01 Sep 2020 13:42:15
User entered '35.54552'	System	01 Sep 2020 13:42:15
User opened query 'BMI \geq 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	System	01 Sep 2020 13:37:36
User entered '78.33301'	System	01 Sep 2020 13:37:36
DataPoint set to visible.	System	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'kg/m2'	System	01 Sep 2020 13:37:36
DataPoint set to visible.	System	01 Sep 2020 13:35:15

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:44:55
User entered '97.2' F	(b) (4), (b) (6)	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty; reason for change Data Entry Error	Brenda Miller (b) (4)	23 Sep 2020 15:44:55
User entered 'Other (Other)'	(b) (4), (b) (6)	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty; reason for change Data Entry Error	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:44:55
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4) System	01 Sep 2020 13:42:15
User entered 'forehead' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 13:42:15
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	01 Sep 2020 13:37:36
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:44:55
User entered '69'	Brenda Miller (b) (4)	01 Sep 2020 13:37:36
	(b) (4), (b) (6)	

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'bpm'	System	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Sep 2020 15:44:55
User entered '20'	Brenda Miller (b) (4)	01 Sep 2020 13:37:36
	(b) (4), (b) (6)	

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'breaths/min'	System	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User closed query ' Per CDM: Response noted. Kindly confirm If Systolic Blood Pressure is clinically significant or non-clinically significant . if it is Clinically significant please enter AE and complete corresponding AE eCRF Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:17:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Miller (b) (4)	23 Sep 2020 15:44:55
Query ' Per CDM: Response noted. Kindly confirm If Systolic Blood Pressure is clinically significant or non-clinically significant . if it is Clinically significant please enter AE and complete corresponding AE eCRF Thank you. ' answered with 'has diagnosis of hypertension, will add to medical history log' (Site from DM).	(b) (4) michelle saemann (b) (4)	23 Sep 2020 15:37:39
User opened query ' Per CDM: Response noted. Kindly confirm If Systolic Blood Pressure is clinically significant or non-clinically significant . if it is Clinically significant please enter AE and complete corresponding AE eCRF Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:00:47
User closed query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 11:00:27
Query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 13:42:31
User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System).	System	01 Sep 2020 13:37:36
User entered '176'	(b) (4), (b) (6)	01 Sep 2020 13:37:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

609 of 3584

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'mmHg'	System	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:18:23
User closed query 'Per CDM: Response noted. Kindly confirm If 'Diastolic Blood Pressure' is clinically significant or non-clinically significant . if it is Clinically significant please enter AE and complete corresponding AE eCRF Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 11:18:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:44:55
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'has diagnosis of hypertension, will add to medical history log' (Site from System).	michelle saemann (b) (4) (b) (4)	23 Sep 2020 15:37:46
Query 'Per CDM: Response noted. Kindly confirm If 'Diastolic Blood Pressure' is clinically significant or non-clinically significant . if it is Clinically significant please enter AE and complete corresponding AE eCRF Thank you.' answered with 'has diagnosis of hypertension, will add to medical history log' (Site from DM).	michelle saemann (b) (4) (b) (4)	23 Sep 2020 15:37:40
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:23:56
User opened query 'Per CDM: Response noted. Kindly confirm If 'Diastolic Blood Pressure' is clinically significant or non-clinically significant . if it is Clinically significant please enter AE and complete corresponding AE eCRF Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 11:04:51

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 11:04:27
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'correct as entered' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 13:42:38
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		01 Sep 2020 13:37:36
User entered '111'	(b) (4), (b) (6)	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User entered 'mmHg'	System	01 Sep 2020 13:37:36

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12

US3662032

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12

US3662032

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:45:14

US3662032

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	Brenda Miller (b) (4)	23 Sep 2020 15:45:14

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

[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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

[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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

[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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'I'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

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 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:19:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:46:02

US3662032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:33

US3662032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	Brenda Miller (b) (4)	23 Sep 2020 15:46:33

US3662032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[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 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:33

US3662032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'VISIT1'	System	23 Sep 2020 15:46:33

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:20:00

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '108265'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:20:00

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:20:00

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

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 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:42

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

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 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:42

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:42

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:42

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 13:43:42

US3662032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:19:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:46:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:52:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:52:33

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:38'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '01 Sep 2020 08:38'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.2' F	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'INFRARED THERMOMETER'	(b) (4)	
reason for change: Data Entry Error	Brenda Miller (b) (4)	23 Sep 2020 23:13:26
User entered 'TEMPORAL'	(b) (4)	
	Brenda Miller (b) (4)	23 Sep 2020 15:49:25
	(b) (4)	

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '69'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'bpm'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '20'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'breaths/min'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '176'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:32:22
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Pt. has dx of hypertension on medical hx form' (Site from System).	michelle saemann (b) (4) (b) (4)	23 Sep 2020 16:12:56
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Sep 2020 15:49:25
User entered '111'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered missing code ND - Not Done.	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User closed query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 09:58, but time of Assessment is 10:19 (21 minutes). Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:16:49
Query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 09:58, but time of Assessment is 10:19 (21 minutes). Please review and update or provide a clarification. Thank you' answered with 'Corrected time to 10:28' (Site from DM).	Brenda Miller (b) (4) (b) (4)	16 Oct 2020 13:08:54
User entered '10:28' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	16 Oct 2020 13:08:35
User opened query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 09:58, but time of Assessment is 10:19 (21 minutes). Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 00:35:23
User entered '10:19'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '01 Sep 2020 10:28'	System	16 Oct 2020 13:08:35
User entered '01 Sep 2020 10:19'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.3' F	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'infrared thermometer' reason for change: Data Entry Error	(b) (4)	
	michelle saemann (b) (4)	23 Sep 2020 16:13:59
User entered 'TEMPORAL'	(b) (4)	
	Brenda Miller (b) (4)	23 Sep 2020 15:49:25
	(b) (4)	

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '59'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'bpm'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '24'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'breaths/min'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '173'	Brenda Miller (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:34:10
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Pt. has history of HTN, see medical hx log. ' (Site from System).	michelle saemann (b) (4) (b) (4)	23 Sep 2020 16:13:38
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Sep 2020 15:49:25
User entered '121'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	23 Sep 2020 15:49:25

US3662032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:51:46

US3662032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:51:46

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User closed query 'Per CDM: Please complete Visit date ,Vitals Signs - Dosing, PE ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for Visit1 Day1 as pages 15-16 per CCGs. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 06:57:06
Query 'Per CDM: Please complete Visit date ,Vitals Signs - Dosing, PE ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for Visit1 Day1 as pages 15-16 per CCGs. Thank you. ' answered with 'All forms completed for Day 1' (Site from DM).	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:54:34
User opened query 'Per CDM: Please complete Visit date ,Vitals Signs - Dosing, PE ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for Visit1 Day1 as pages 15-16 per CCGs. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 11:20:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

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 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '09:58' reason for change: Data Entry Error	System	01 Sep 2020 14:13:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 14:13:24
User entered '09:' (non-conformant).		
	(b) (4), (b) (6)	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '01 Sep 2020 09:58'	System	01 Sep 2020 14:13:24
User entered '01 Sep 2020 09:' (non-conformant).	System	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'ONCE'	System	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 14:13:16

US3662032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:53:26

US3662032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	Brenda Miller (b) (4)	23 Sep 2020 15:53:26

US3662032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:15'	Brenda Miller (b) (4)	23 Sep 2020 15:53:26

US3662032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '01 Sep 2020 08:15'	System	23 Sep 2020 15:53:26

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '01 Sep 2020'	Brenda Miller (b) (4)	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:35'	Brenda Miller (b) (4)	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered '01 Sep 2020 08:35'	System	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered empty.	System	23 Sep 2020 15:53:56

US3662032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:54:08

US3662032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered 'I'	System	23 Sep 2020 15:54:08

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:19:17', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8d76f48f-eddf-4ab6-a3c7-29a1bf7e9e7c' User entered 'Yes (Y)'	System	01 Sep 2020 14:21:32
	System	01 Sep 2020 14:21:32

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:20:39', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8d76f48f-eddf-4ab6-a3c7-29a1bf7e9e7c' User entered '97.3'	System	01 Sep 2020 14:21:32
	System	01 Sep 2020 14:21:32

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:20:48', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8d76f48f-eddf-4ab6-a3c7-29a1bf7e9e7c'	System	01 Sep 2020 14:21:32
User entered 'No (N)'	System	01 Sep 2020 14:21:32

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:21:26', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8d76f48f-eddf-4ab6-a3c7-29a1bf7e9e7c' User entered '01 Sep 2020 10:21'	System	01 Sep 2020 14:21:32
	System	01 Sep 2020 14:21:32

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 10:18'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 12:48'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:51', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '44d0bc4c-9385-4520-aa3c-ca187a9981c4' User entered 'Yes (Y)'	System	01 Sep 2020 17:45:07
	System	01 Sep 2020 17:45:07

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:58', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '44d0bc4c-9385-4520-aa3c-ca187a9981c4' User entered '98.3'	System	01 Sep 2020 17:45:07
	System	01 Sep 2020 17:45:07

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:45:02', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '44d0bc4c-9385-4520-aa3c-ca187a9981c4' User entered 'No (N)'	System	01 Sep 2020 17:45:07
	System	01 Sep 2020 17:45:07

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:45:04', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '44d0bc4c-9385-4520-aa3c-ca187a9981c4' User entered '01 Sep 2020 13:45'	System	01 Sep 2020 17:45:07
	System	01 Sep 2020 17:45:07

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 13:43'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 2'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:12', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2d06e212-bcd4-4704-9705-1da6184b23cc' User entered 'Yes (Y)'	System	02 Sep 2020 16:11:29
	System	02 Sep 2020 16:11:29

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:18', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2d06e212-bcd4-4704-9705-1da6184b23cc' User entered '98.2'	System	02 Sep 2020 16:11:29
	System	02 Sep 2020 16:11:29

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:23', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2d06e212-bcd4-4704-9705-1da6184b23cc' User entered 'No (N)'	System	02 Sep 2020 16:11:29
	System	02 Sep 2020 16:11:29

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:28', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2d06e212-bcd4-4704-9705-1da6184b23cc' User entered '02 Sep 2020 12:11'	System	02 Sep 2020 16:11:29
	System	02 Sep 2020 16:11:29

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 3'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:00:30', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '94d4508f-fde0-4b38-97fb-4eb12268924e' User entered 'Yes (Y)'	System	03 Sep 2020 16:01:11
	System	03 Sep 2020 16:01:11

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:00:37', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '94d4508f-fde0-4b38-97fb-4eb12268924e' User entered '98.2'	System	03 Sep 2020 16:01:11
	System	03 Sep 2020 16:01:11

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:00:40', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '94d4508f-fde0-4b38-97fb-4eb12268924e' User entered 'No (N)'	System	03 Sep 2020 16:01:11
	System	03 Sep 2020 16:01:11

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:00:46', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '94d4508f-fde0-4b38-97fb-4eb12268924e' User entered '03 Sep 2020 12:00'	System	03 Sep 2020 16:01:11
	System	03 Sep 2020 16:01:11

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 4'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:11:53', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '6b3b2457-70e7-4aed-9c18-18ebc63c11fa' User entered 'Yes (Y)'	System	04 Sep 2020 19:12:07
	System	04 Sep 2020 19:12:07

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:11:59', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '6b3b2457-70e7-4aed-9c18-18ebc63c11fa' User entered '98.2'	System	04 Sep 2020 19:12:07
	System	04 Sep 2020 19:12:07

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:02', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '6b3b2457-70e7-4aed-9c18-18ebc63c11fa' User entered 'No (N)'	System	04 Sep 2020 19:12:07
	System	04 Sep 2020 19:12:07

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:05', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '6b3b2457-70e7-4aed-9c18-18ebc63c11fa' User entered '04 Sep 2020 15:12'	System	04 Sep 2020 19:12:07
	System	04 Sep 2020 19:12:07

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 5'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:19', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '5c390f1a-838f-49c4-91b4-bf99841c8689' User entered 'Yes (Y)'	System	06 Sep 2020 13:35:35
	System	06 Sep 2020 13:35:35

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:25', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '5c390f1a-838f-49c4-91b4-bf99841c8689' User entered '98.1'	System	06 Sep 2020 13:35:35
	System	06 Sep 2020 13:35:35

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:30', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '5c390f1a-838f-49c4-91b4-bf99841c8689'	System	06 Sep 2020 13:35:35
User entered 'No (N)'	System	06 Sep 2020 13:35:35

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:34', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '5c390f1a-838f-49c4-91b4-bf99841c8689' User entered '06 Sep 2020 09:35'	System	06 Sep 2020 13:35:35
	System	06 Sep 2020 13:35:35

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 6'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:05:05', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7a9745f8-3d75-41bd-98de-819753dc60e1' User entered 'Yes (Y)'	System	07 Sep 2020 12:05:40
	System	07 Sep 2020 12:05:40

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:05:16', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7a9745f8-3d75-41bd-98de-819753dc60e1' User entered '98.2'	System	07 Sep 2020 12:05:40
	System	07 Sep 2020 12:05:40

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:05:32', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7a9745f8-3d75-41bd-98de-819753dc60e1' User entered 'No (N)'	System	07 Sep 2020 12:05:40
	System	07 Sep 2020 12:05:40

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:05:36', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7a9745f8-3d75-41bd-98de-819753dc60e1' User entered '07 Sep 2020 08:05'	System	07 Sep 2020 12:05:40
	System	07 Sep 2020 12:05:40

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 7'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:20:49', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c8d699c0-d71c-44a7-b204-494c00471763' User entered 'Yes (Y)'	System	08 Sep 2020 14:21:04
	System	08 Sep 2020 14:21:04

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:20:55', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c8d699c0-d71c-44a7-b204-494c00471763' User entered '98.2'	System	08 Sep 2020 14:21:04
	System	08 Sep 2020 14:21:04

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:20:57', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c8d699c0-d71c-44a7-b204-494c00471763' User entered 'No (N)'	System	08 Sep 2020 14:21:04
	System	08 Sep 2020 14:21:04

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c8d699c0-d71c-44a7-b204-494c00471763' User entered '08 Sep 2020 10:21'	System	08 Sep 2020 14:21:04
	System	08 Sep 2020 14:21:04

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:21:52', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8faba6de-9189-4d0f-93d4-0e414a36dc7b' User entered 'None (1)'	System	01 Sep 2020 14:22:27
	System	01 Sep 2020 14:22:27

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:21:55', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8faba6de-9189-4d0f-93d4-0e414a36dc7b' User entered 'No (N)'	System	01 Sep 2020 14:22:27
	System	01 Sep 2020 14:22:27

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:02', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8faba6de-9189-4d0f-93d4-0e414a36dc7b' User entered 'No (N)'	System	01 Sep 2020 14:22:27
	System	01 Sep 2020 14:22:27

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8faba6de-9189-4d0f-93d4-0e414a36dc7b' User entered 'None (1)'	System	01 Sep 2020 14:22:27
	System	01 Sep 2020 14:22:27

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:22', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8faba6de-9189-4d0f-93d4-0e414a36dc7b' User entered '01 Sep 2020 10:22'	System	01 Sep 2020 14:22:27
	System	01 Sep 2020 14:22:27

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 10:18'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 12:48'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:43:42', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '361c4268-424f-4389-90cb-8bc335c152fd' User entered 'None (1)'	System	01 Sep 2020 17:44:08
	System	01 Sep 2020 17:44:08

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:43:45', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '361c4268-424f-4389-90cb-8bc335c152fd' User entered 'No (N)'	System	01 Sep 2020 17:44:08
	System	01 Sep 2020 17:44:08

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:43:53', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '361c4268-424f-4389-90cb-8bc335c152fd' User entered 'No (N)'	System	01 Sep 2020 17:44:08
	System	01 Sep 2020 17:44:08

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:43:57', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '361c4268-424f-4389-90cb-8bc335c152fd' User entered 'None (1)'	System	01 Sep 2020 17:44:08
	System	01 Sep 2020 17:44:08

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:02', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '361c4268-424f-4389-90cb-8bc335c152fd' User entered '01 Sep 2020 13:44'	System	01 Sep 2020 17:44:08
	System	01 Sep 2020 17:44:08

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 13:43'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 2'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:32', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '706fdd53-8fa4-4c08-b408-7a5e83c61587'	System	02 Sep 2020 16:11:44
User entered 'None (1)'	System	02 Sep 2020 16:11:44

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:34', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '706fdd53-8fa4-4c08-b408-7a5e83c61587'	System	02 Sep 2020 16:11:44
User entered 'No (N)'	System	02 Sep 2020 16:11:44

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:37', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '706fdd53-8fa4-4c08-b408-7a5e83c61587'	System	02 Sep 2020 16:11:44
User entered 'No (N)'	System	02 Sep 2020 16:11:44

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:40', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '706fdd53-8fa4-4c08-b408-7a5e83c61587'	System	02 Sep 2020 16:11:44
User entered 'None (1)'	System	02 Sep 2020 16:11:44

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:42', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '706fdd53-8fa4-4c08-b408-7a5e83c61587'	System	02 Sep 2020 16:11:44
User entered '02 Sep 2020 12:11'	System	02 Sep 2020 16:11:44

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 3'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:00:50', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b8d94766-faed-4a2d-9b66-a1bc6619e4ae' User entered 'None (1)'	System	03 Sep 2020 16:02:14
	System	03 Sep 2020 16:02:14

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:00:56', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b8d94766-faed-4a2d-9b66-a1bc6619e4ae' User entered 'No (N)'	System	03 Sep 2020 16:02:14
	System	03 Sep 2020 16:02:14

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:03', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b8d94766-faed-4a2d-9b66-a1bc6619e4ae' User entered 'No (N)'	System	03 Sep 2020 16:02:14
	System	03 Sep 2020 16:02:14

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:05', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b8d94766-faed-4a2d-9b66-a1bc6619e4ae' User entered 'None (1)'	System	03 Sep 2020 16:02:14
	System	03 Sep 2020 16:02:14

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:09', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b8d94766-faed-4a2d-9b66-a1bc6619e4ae' User entered '03 Sep 2020 12:01'	System	03 Sep 2020 16:02:14
	System	03 Sep 2020 16:02:14

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 4'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:08', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a6bd0c6f-b79e-41dc-a5a9-fa5305ef8085'	System	04 Sep 2020 19:12:21
User entered 'None (1)'	System	04 Sep 2020 19:12:21

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a6bd0c6f-b79e-41dc-a5a9-fa5305ef8085'	System	04 Sep 2020 19:12:21
User entered 'No (N)'	System	04 Sep 2020 19:12:21

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:13', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a6bd0c6f-b79e-41dc-a5a9-fa5305ef8085' User entered 'No (N)'	System	04 Sep 2020 19:12:21
	System	04 Sep 2020 19:12:21

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:15', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a6bd0c6f-b79e-41dc-a5a9-fa5305ef8085'	System	04 Sep 2020 19:12:21
User entered 'None (1)'	System	04 Sep 2020 19:12:21

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:16', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a6bd0c6f-b79e-41dc-a5a9-fa5305ef8085' User entered '04 Sep 2020 15:12'	System	04 Sep 2020 19:12:21
	System	04 Sep 2020 19:12:21

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 5'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:37', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c5fc4974-b10c-4cc1-9df9-d70e56f98794'	System	06 Sep 2020 13:35:57
User entered 'None (1)'	System	06 Sep 2020 13:35:57

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:40', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c5fc4974-b10c-4cc1-9df9-d70e56f98794'	System	06 Sep 2020 13:35:57
User entered 'No (N)'	System	06 Sep 2020 13:35:57

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:42', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c5fc4974-b10c-4cc1-9df9-d70e56f98794'	System	06 Sep 2020 13:35:57
User entered 'No (N)'	System	06 Sep 2020 13:35:57

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:46', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c5fc4974-b10c-4cc1-9df9-d70e56f98794'	System	06 Sep 2020 13:35:57
User entered 'None (1)'	System	06 Sep 2020 13:35:57

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'c5fc4974-b10c-4cc1-9df9-d70e56f98794'	System	06 Sep 2020 13:35:57
User entered '06 Sep 2020 09:35'	System	06 Sep 2020 13:35:57

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 6'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:05:39', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8910a551-a842-4e90-b33b-4fabb716cf47'	System	07 Sep 2020 12:06:03
User entered 'None (1)'	System	07 Sep 2020 12:06:03

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:05:44', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8910a551-a842-4e90-b33b-4fabb716cf47'	System	07 Sep 2020 12:06:03
User entered 'No (N)'	System	07 Sep 2020 12:06:03

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:05:48', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8910a551-a842-4e90-b33b-4fabb716cf47'	System	07 Sep 2020 12:06:03
User entered 'No (N)'	System	07 Sep 2020 12:06:03

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:05:59', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8910a551-a842-4e90-b33b-4fabb716cf47'	System	07 Sep 2020 12:06:03
User entered 'None (1)'	System	07 Sep 2020 12:06:03

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8910a551-a842-4e90-b33b-4fabb716cf47' User entered '07 Sep 2020 08:06'	System	07 Sep 2020 12:06:03
	System	07 Sep 2020 12:06:03

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 7'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:06', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '06a9ee26-6e8f-4b8a-b109-b00b96a4f42f' User entered 'None (1)'	System	08 Sep 2020 14:21:36
	System	08 Sep 2020 14:21:36

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:10', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '06a9ee26-6e8f-4b8a-b109-b00b96a4f42f' User entered 'No (N)'	System	08 Sep 2020 14:21:36
	System	08 Sep 2020 14:21:36

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:24', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '06a9ee26-6e8f-4b8a-b109-b00b96a4f42f' User entered 'No (N)'	System	08 Sep 2020 14:21:36
	System	08 Sep 2020 14:21:36

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:28', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '06a9ee26-6e8f-4b8a-b109-b00b96a4f42f' User entered 'None (1)'	System	08 Sep 2020 14:21:36
	System	08 Sep 2020 14:21:36

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:33', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '06a9ee26-6e8f-4b8a-b109-b00b96a4f42f' User entered '08 Sep 2020 10:21'	System	08 Sep 2020 14:21:36
	System	08 Sep 2020 14:21:36

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:31', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'd0a68325-b939-4b8c-a421-93c6e77d6f8c' User entered 'None (0)'	System	01 Sep 2020 14:23:06
	System	01 Sep 2020 14:23:06

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:34', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'd0a68325-b939-4b8c-a421-93c6e77d6f8c' User entered 'None (0)'	System	01 Sep 2020 14:23:06
	System	01 Sep 2020 14:23:06

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:37', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'd0a68325-b939-4b8c-a421-93c6e77d6f8c' User entered 'None (0)'	System	01 Sep 2020 14:23:06
	System	01 Sep 2020 14:23:06

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:45', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'd0a68325-b939-4b8c-a421-93c6e77d6f8c' User entered 'None (0)'	System	01 Sep 2020 14:23:06
	System	01 Sep 2020 14:23:06

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:48', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'd0a68325-b939-4b8c-a421-93c6e77d6f8c' User entered 'None (0)'	System	01 Sep 2020 14:23:06
	System	01 Sep 2020 14:23:06

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:51', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'd0a68325-b939-4b8c-a421-93c6e77d6f8c' User entered 'None (0)'	System	01 Sep 2020 14:23:06
	System	01 Sep 2020 14:23:06

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:22:56', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'd0a68325-b939-4b8c-a421-93c6e77d6f8c' User entered 'No (N)'	System	01 Sep 2020 14:23:06
	System	01 Sep 2020 14:23:06

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T10:23:04', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'd0a68325-b939-4b8c-a421-93c6e77d6f8c' User entered '01 Sep 2020 10:23'	System	01 Sep 2020 14:23:06
	System	01 Sep 2020 14:23:06

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 10:18'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 12:48'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:08', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '95c2bd0a-24a1-4876-a49b-6a7aa0729cfb' User entered 'None (0)'	System	01 Sep 2020 17:44:39
	System	01 Sep 2020 17:44:39

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '95c2bd0a-24a1-4876-a49b-6a7aa0729cfb' User entered 'None (0)'	System	01 Sep 2020 17:44:39
	System	01 Sep 2020 17:44:39

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:14', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '95c2bd0a-24a1-4876-a49b-6a7aa0729cfb' User entered 'None (0)'	System	01 Sep 2020 17:44:39
	System	01 Sep 2020 17:44:39

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:17', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '95c2bd0a-24a1-4876-a49b-6a7aa0729cfb' User entered 'None (0)'	System	01 Sep 2020 17:44:39
	System	01 Sep 2020 17:44:39

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:20', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '95c2bd0a-24a1-4876-a49b-6a7aa0729cfb' User entered 'None (0)'	System	01 Sep 2020 17:44:39
	System	01 Sep 2020 17:44:39

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:22', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '95c2bd0a-24a1-4876-a49b-6a7aa0729cfb' User entered 'None (0)'	System	01 Sep 2020 17:44:39
	System	01 Sep 2020 17:44:39

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:31', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '95c2bd0a-24a1-4876-a49b-6a7aa0729cfb' User entered 'No (N)'	System	01 Sep 2020 17:44:39
	System	01 Sep 2020 17:44:39

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-01T13:44:37', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '95c2bd0a-24a1-4876-a49b-6a7aa0729cfb' User entered '01 Sep 2020 13:44'	System	01 Sep 2020 17:44:39
	System	01 Sep 2020 17:44:39

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Sep 2020 13:43'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 2'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:52', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '18874d83-f395-463d-bc66-69bb56ada6a5' User entered 'None (0)'	System	02 Sep 2020 16:12:11
	System	02 Sep 2020 16:12:11

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '18874d83-f395-463d-bc66-69bb56ada6a5' User entered 'None (0)'	System	02 Sep 2020 16:12:11
	System	02 Sep 2020 16:12:11

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:56', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '18874d83-f395-463d-bc66-69bb56ada6a5' User entered 'None (0)'	System	02 Sep 2020 16:12:11
	System	02 Sep 2020 16:12:11

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:11:59', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '18874d83-f395-463d-bc66-69bb56ada6a5' User entered 'None (0)'	System	02 Sep 2020 16:12:11
	System	02 Sep 2020 16:12:11

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:12:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '18874d83-f395-463d-bc66-69bb56ada6a5' User entered 'None (0)'	System	02 Sep 2020 16:12:11
	System	02 Sep 2020 16:12:11

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:12:03', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '18874d83-f395-463d-bc66-69bb56ada6a5' User entered 'None (0)'	System	02 Sep 2020 16:12:11
	System	02 Sep 2020 16:12:11

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:12:06', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '18874d83-f395-463d-bc66-69bb56ada6a5' User entered 'No (N)'	System	02 Sep 2020 16:12:11
	System	02 Sep 2020 16:12:11

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-02T12:12:08', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '18874d83-f395-463d-bc66-69bb56ada6a5' User entered '02 Sep 2020 12:12'	System	02 Sep 2020 16:12:11
	System	02 Sep 2020 16:12:11

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 3'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:13', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7ec6b1e1-13d6-4e35-a979-6de8c8dd7100' User entered 'None (0)'	System	03 Sep 2020 16:03:27
	System	03 Sep 2020 16:03:27

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:15', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7ec6b1e1-13d6-4e35-a979-6de8c8dd7100' User entered 'None (0)'	System	03 Sep 2020 16:03:27
	System	03 Sep 2020 16:03:27

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:17', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7ec6b1e1-13d6-4e35-a979-6de8c8dd7100' User entered 'None (0)'	System	03 Sep 2020 16:03:27
	System	03 Sep 2020 16:03:27

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:18', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7ec6b1e1-13d6-4e35-a979-6de8c8dd7100' User entered 'None (0)'	System	03 Sep 2020 16:03:27
	System	03 Sep 2020 16:03:27

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:21', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7ec6b1e1-13d6-4e35-a979-6de8c8dd7100' User entered 'None (0)'	System	03 Sep 2020 16:03:27
	System	03 Sep 2020 16:03:27

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:22', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7ec6b1e1-13d6-4e35-a979-6de8c8dd7100' User entered 'None (0)'	System	03 Sep 2020 16:03:27
	System	03 Sep 2020 16:03:27

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:48', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7ec6b1e1-13d6-4e35-a979-6de8c8dd7100' User entered 'No (N)'	System	03 Sep 2020 16:03:27
	System	03 Sep 2020 16:03:27

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-03T12:01:51', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7ec6b1e1-13d6-4e35-a979-6de8c8dd7100' User entered '03 Sep 2020 12:01'	System	03 Sep 2020 16:03:27
	System	03 Sep 2020 16:03:27

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 4'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:20', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4e8fe1bc-60e2-4465-ad15-99893a77896e' User entered 'None (0)'	System	04 Sep 2020 19:12:42
	System	04 Sep 2020 19:12:42

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:21', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4e8fe1bc-60e2-4465-ad15-99893a77896e' User entered 'None (0)'	System	04 Sep 2020 19:12:42
	System	04 Sep 2020 19:12:42

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:25', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4e8fe1bc-60e2-4465-ad15-99893a77896e' User entered 'None (0)'	System	04 Sep 2020 19:12:42
	System	04 Sep 2020 19:12:42

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:28', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4e8fe1bc-60e2-4465-ad15-99893a77896e' User entered 'None (0)'	System	04 Sep 2020 19:12:42
	System	04 Sep 2020 19:12:42

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:31', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4e8fe1bc-60e2-4465-ad15-99893a77896e' User entered 'None (0)'	System	04 Sep 2020 19:12:42
	System	04 Sep 2020 19:12:42

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:33', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4e8fe1bc-60e2-4465-ad15-99893a77896e' User entered 'None (0)'	System	04 Sep 2020 19:12:42
	System	04 Sep 2020 19:12:42

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:36', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4e8fe1bc-60e2-4465-ad15-99893a77896e' User entered 'No (N)'	System	04 Sep 2020 19:12:42
	System	04 Sep 2020 19:12:42

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-04T15:12:38', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4e8fe1bc-60e2-4465-ad15-99893a77896e' User entered '04 Sep 2020 15:12'	System	04 Sep 2020 19:12:42
	System	04 Sep 2020 19:12:42

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 5'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:58', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '87f7ffb0-32e1-4e6f-8242-780a37b76bc6' User entered 'None (0)'	System	06 Sep 2020 13:36:16
	System	06 Sep 2020 13:36:16

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:35:59', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '87f7ffb0-32e1-4e6f-8242-780a37b76bc6' User entered 'None (0)'	System	06 Sep 2020 13:36:16
	System	06 Sep 2020 13:36:16

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:36:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '87f7ffb0-32e1-4e6f-8242-780a37b76bc6' User entered 'None (0)'	System	06 Sep 2020 13:36:16
	System	06 Sep 2020 13:36:16

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:36:03', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '87f7ffb0-32e1-4e6f-8242-780a37b76bc6' User entered 'None (0)'	System	06 Sep 2020 13:36:16
	System	06 Sep 2020 13:36:16

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:36:05', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '87f7ffb0-32e1-4e6f-8242-780a37b76bc6' User entered 'None (0)'	System	06 Sep 2020 13:36:16
	System	06 Sep 2020 13:36:16

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:36:06', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '87f7ffb0-32e1-4e6f-8242-780a37b76bc6' User entered 'None (0)'	System	06 Sep 2020 13:36:16
	System	06 Sep 2020 13:36:16

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:36:10', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '87f7ffb0-32e1-4e6f-8242-780a37b76bc6'	System	06 Sep 2020 13:36:16
User entered 'No (N)'	System	06 Sep 2020 13:36:16

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-06T09:36:12', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '87f7ffb0-32e1-4e6f-8242-780a37b76bc6' User entered '06 Sep 2020 09:36'	System	06 Sep 2020 13:36:16
	System	06 Sep 2020 13:36:16

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 6'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:05', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '32e230fd-ac21-43d7-a85e-f7d7fcef57d0' User entered 'None (0)'	System	07 Sep 2020 12:06:25
	System	07 Sep 2020 12:06:25

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:07', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '32e230fd-ac21-43d7-a85e-f7d7fcef57d0' User entered 'None (0)'	System	07 Sep 2020 12:06:25
	System	07 Sep 2020 12:06:25

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:09', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '32e230fd-ac21-43d7-a85e-f7d7fcef57d0' User entered 'None (0)'	System	07 Sep 2020 12:06:25
	System	07 Sep 2020 12:06:25

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '32e230fd-ac21-43d7-a85e-f7d7fcef57d0' User entered 'None (0)'	System	07 Sep 2020 12:06:25
	System	07 Sep 2020 12:06:25

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:13', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '32e230fd-ac21-43d7-a85e-f7d7fcef57d0' User entered 'None (0)'	System	07 Sep 2020 12:06:25
	System	07 Sep 2020 12:06:25

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:15', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '32e230fd-ac21-43d7-a85e-f7d7fcef57d0' User entered 'None (0)'	System	07 Sep 2020 12:06:25
	System	07 Sep 2020 12:06:25

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:19', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '32e230fd-ac21-43d7-a85e-f7d7fcef57d0' User entered 'No (N)'	System	07 Sep 2020 12:06:25
	System	07 Sep 2020 12:06:25

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-07T08:06:21', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '32e230fd-ac21-43d7-a85e-f7d7fcef57d0' User entered '07 Sep 2020 08:06'	System	07 Sep 2020 12:06:25
	System	07 Sep 2020 12:06:25

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 7'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:38', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ee0a687c-a4fd-4963-86ed-f7357a5ba847' User entered 'None (0)'	System	08 Sep 2020 14:22:00
	System	08 Sep 2020 14:22:00

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:40', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ee0a687c-a4fd-4963-86ed-f7357a5ba847' User entered 'None (0)'	System	08 Sep 2020 14:22:00
	System	08 Sep 2020 14:22:00

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:44', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ee0a687c-a4fd-4963-86ed-f7357a5ba847' User entered 'None (0)'	System	08 Sep 2020 14:22:00
	System	08 Sep 2020 14:22:00

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:48', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ee0a687c-a4fd-4963-86ed-f7357a5ba847' User entered 'None (0)'	System	08 Sep 2020 14:22:00
	System	08 Sep 2020 14:22:00

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:50', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ee0a687c-a4fd-4963-86ed-f7357a5ba847' User entered 'None (0)'	System	08 Sep 2020 14:22:00
	System	08 Sep 2020 14:22:00

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:51', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ee0a687c-a4fd-4963-86ed-f7357a5ba847' User entered 'None (0)'	System	08 Sep 2020 14:22:00
	System	08 Sep 2020 14:22:00

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ee0a687c-a4fd-4963-86ed-f7357a5ba847'	System	08 Sep 2020 14:22:00
User entered 'No (N)'	System	08 Sep 2020 14:22:00

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-08T10:21:57', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ee0a687c-a4fd-4963-86ed-f7357a5ba847' User entered '08 Sep 2020 10:21'	System	08 Sep 2020 14:22:00
	System	08 Sep 2020 14:22:00

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 14:13:24

US3662032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 16:02:31

US3662032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08 Sep 2020'	Brenda Miller (b) (4)	23 Sep 2020 16:02:31

US3662032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	23 Sep 2020 16:02:31

US3662032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 16:02:31

US3662032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 16:02:40

US3662032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered 'I'	System	23 Sep 2020 16:02:40

US3662032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 16:03:01

US3662032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '15 Sep 2020'	Brenda Miller (b) (4)	23 Sep 2020 16:03:01

US3662032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	23 Sep 2020 16:03:01

US3662032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 16:03:01

US3662032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 16:03:24

US3662032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered 'I'	System	23 Sep 2020 16:03:24

US3662032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 16:03:47

US3662032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '22 Sep 2020'	Brenda Miller (b) (4)	23 Sep 2020 16:03:47

US3662032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	23 Sep 2020 16:03:47

US3662032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 16:03:47

US3662032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 12:36:12

US3662032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered 'I'	System	29 Sep 2020 12:36:12

US3662032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 15:43:39

US3662032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '29 Sep 2020'	(b) (4) Brenda Miller (b) (4)	02 Oct 2020 15:43:39

US3662032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[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 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	02 Oct 2020 15:43:39

US3662032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'VISIT2'	System	02 Oct 2020 15:43:39

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '29 Sep 2020'	(b) (4) Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:11'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '29 Sep 2020 08:11'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.6' F	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '68'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'bpm'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '16'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'breaths/min'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '160'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '92'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '29 Sep 2020'	(b) (4) Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '09:45'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '29 Sep 2020 09:45'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.7' F	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '66'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'bpm'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '16'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'breaths/min'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '158'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '100'	Brenda Miller (b) (4)	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	02 Oct 2020 15:45:53

US3662032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 15:46:14

US3662032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '29 Sep 2020'	Brenda Miller (b) (4)	02 Oct 2020 15:46:14

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

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 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '09:15'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '29 Sep 2020 09:15'	System	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'ONCE'	System	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 13:17:00

US3662032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 15:46:45

US3662032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '29 Sep 2020'	(b) (4) Brenda Miller (b) (4)	02 Oct 2020 15:46:45

US3662032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '09:05'	Brenda Miller (b) (4)	02 Oct 2020 15:46:45

US3662032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '29 Sep 2020 09:05'	System	02 Oct 2020 15:46:45

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '29 Sep 2020'	Brenda Miller (b) (4)	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '09:00'	Brenda Miller (b) (4)	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '29 Sep 2020 09:00'	System	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered empty.	System	02 Oct 2020 15:47:02

US3662032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	09 Oct 2020 19:18:41

US3662032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'I'	System	09 Oct 2020 19:18:41

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:36:25', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '61929f72-819e-438b-a7e6-2eaebf47f069'	System	29 Sep 2020 13:37:01
User entered 'Yes (Y)'	System	29 Sep 2020 13:37:01

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:36:49', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '61929f72-819e-438b-a7e6-2eae47f069' User entered '97.7'	System	29 Sep 2020 13:37:01
	System	29 Sep 2020 13:37:01

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:36:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '61929f72-819e-438b-a7e6-2eae47f069'	System	29 Sep 2020 13:37:01
User entered 'No (N)'	System	29 Sep 2020 13:37:01

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:36:58', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '61929f72-819e-438b-a7e6-2eae47f069' User entered '29 Sep 2020 09:36'	System	29 Sep 2020 13:37:01
	System	29 Sep 2020 13:37:01

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 09:35'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 12:05'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:02:35', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '604346cb-8fae-41e1-b461-9669cc034e02' User entered 'Yes (Y)'	System	30 Sep 2020 11:02:57
	System	30 Sep 2020 11:02:57

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:02:45', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '604346cb-8fae-41e1-b461-9669cc034e02' User entered '98.1'	System	30 Sep 2020 11:02:57
	System	30 Sep 2020 11:02:57

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:02:52', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '604346cb-8fae-41e1-b461-9669cc034e02' User entered 'No (N)'	System	30 Sep 2020 11:02:57
	System	30 Sep 2020 11:02:57

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:02:56', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '604346cb-8fae-41e1-b461-9669cc034e02' User entered '30 Sep 2020 07:02'	System	30 Sep 2020 11:02:57
	System	30 Sep 2020 11:02:57

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 13:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 2'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:01:36', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '236696ee-5386-4a98-8cd8-ba6d09a688eb' User entered 'Yes (Y)'	System	01 Oct 2020 10:01:55
	System	01 Oct 2020 10:01:55

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:01:47', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '236696ee-5386-4a98-8cd8-ba6d09a688eb' User entered '97.1'	System	01 Oct 2020 10:01:55
	System	01 Oct 2020 10:01:55

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:01:50', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '236696ee-5386-4a98-8cd8-ba6d09a688eb' User entered 'No (N)'	System	01 Oct 2020 10:01:55
	System	01 Oct 2020 10:01:55

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:01:53', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '236696ee-5386-4a98-8cd8-ba6d09a688eb' User entered '01 Oct 2020 06:01'	System	01 Oct 2020 10:01:55
	System	01 Oct 2020 10:01:55

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 3'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T05:59:39', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f5a816aa-6121-4a2f-a769-b5ef8ee0637d' User entered 'Yes (Y)'	System	02 Oct 2020 09:59:57
	System	02 Oct 2020 09:59:57

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T05:59:44', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f5a816aa-6121-4a2f-a769-b5ef8ee0637d' User entered '97.2'	System	02 Oct 2020 09:59:57
	System	02 Oct 2020 09:59:57

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T05:59:50', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f5a816aa-6121-4a2f-a769-b5ef8ee0637d' User entered 'No (N)'	System	02 Oct 2020 09:59:57
	System	02 Oct 2020 09:59:57

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T05:59:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f5a816aa-6121-4a2f-a769-b5ef8ee0637d' User entered '02 Oct 2020 05:59'	System	02 Oct 2020 09:59:57
	System	02 Oct 2020 09:59:57

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 4'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:37:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '33ac92f4-94b0-4c2e-a166-4496fd1f4bb8' User entered 'Yes (Y)'	System	03 Oct 2020 07:38:13
	System	03 Oct 2020 07:38:13

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '33ac92f4-94b0-4c2e-a166-4496fd1f4bb8' User entered '97.2'	System	03 Oct 2020 07:38:13
	System	03 Oct 2020 07:38:13

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:05', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '33ac92f4-94b0-4c2e-a166-4496fd1f4bb8'	System	03 Oct 2020 07:38:13
User entered 'No (N)'	System	03 Oct 2020 07:38:13

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:10', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '33ac92f4-94b0-4c2e-a166-4496fd1f4bb8' User entered '03 Oct 2020 03:38'	System	03 Oct 2020 07:38:13
	System	03 Oct 2020 07:38:13

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 5'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T05:59:32', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'bca8d443-4841-43a6-a736-98b06128099a' User entered 'Yes (Y)'	System	04 Oct 2020 09:59:51
	System	04 Oct 2020 09:59:51

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T05:59:38', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'bca8d443-4841-43a6-a736-98b06128099a' User entered '97.3'	System	04 Oct 2020 09:59:51
	System	04 Oct 2020 09:59:51

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T05:59:42', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'bca8d443-4841-43a6-a736-98b06128099a' User entered 'No (N)'	System	04 Oct 2020 09:59:51
	System	04 Oct 2020 09:59:51

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T05:59:49', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'bca8d443-4841-43a6-a736-98b06128099a' User entered '04 Oct 2020 05:59'	System	04 Oct 2020 09:59:51
	System	04 Oct 2020 09:59:51

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 6'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:55:33', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '23e889af-95a4-46f5-bbdb-c0eedd2e0251' User entered 'Yes (Y)'	System	05 Oct 2020 09:56:10
	System	05 Oct 2020 09:56:10

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:55:42', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '23e889af-95a4-46f5-bbdb-c0eedd2e0251' User entered '97.2'	System	05 Oct 2020 09:56:10
	System	05 Oct 2020 09:56:10

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:55:50', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '23e889af-95a4-46f5-bbdb-c0eedd2e0251' User entered 'No (N)'	System	05 Oct 2020 09:56:10
	System	05 Oct 2020 09:56:10

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:55:53', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '23e889af-95a4-46f5-bbdb-c0eedd2e0251' User entered '05 Oct 2020 05:55'	System	05 Oct 2020 09:56:10
	System	05 Oct 2020 09:56:10

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 7'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:14', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '825c6c88-a30b-451c-80fc-92a00a796889' User entered 'Yes (Y)'	System	06 Oct 2020 11:14:35
	System	06 Oct 2020 11:14:35

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:22', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '825c6c88-a30b-451c-80fc-92a00a796889' User entered '97.1'	System	06 Oct 2020 11:14:35
	System	06 Oct 2020 11:14:35

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:27', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '825c6c88-a30b-451c-80fc-92a00a796889' User entered 'No (N)'	System	06 Oct 2020 11:14:35
	System	06 Oct 2020 11:14:35

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:30', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '825c6c88-a30b-451c-80fc-92a00a796889' User entered '06 Oct 2020 07:14'	System	06 Oct 2020 11:14:35
	System	06 Oct 2020 11:14:35

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:37:17', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8438f784-66ea-46a2-9d45-9e82a3e4233a' User entered 'None (1)'	System	29 Sep 2020 13:37:54
	System	29 Sep 2020 13:37:54

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:37:20', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8438f784-66ea-46a2-9d45-9e82a3e4233a' User entered 'No (N)'	System	29 Sep 2020 13:37:54
	System	29 Sep 2020 13:37:54

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:37:45', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8438f784-66ea-46a2-9d45-9e82a3e4233a' User entered 'No (N)'	System	29 Sep 2020 13:37:54
	System	29 Sep 2020 13:37:54

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:37:49', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8438f784-66ea-46a2-9d45-9e82a3e4233a' User entered 'None (1)'	System	29 Sep 2020 13:37:54
	System	29 Sep 2020 13:37:54

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:37:52', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '8438f784-66ea-46a2-9d45-9e82a3e4233a' User entered '29 Sep 2020 09:37'	System	29 Sep 2020 13:37:54
	System	29 Sep 2020 13:37:54

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 09:35'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 12:05'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:04', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ab422e44-2375-45f9-b48c-71eb70e99ff9'	System	30 Sep 2020 11:03:21
User entered 'None (1)'	System	30 Sep 2020 11:03:21

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:07', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ab422e44-2375-45f9-b48c-71eb70e99ff9' User entered 'No (N)'	System	30 Sep 2020 11:03:21
	System	30 Sep 2020 11:03:21

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ab422e44-2375-45f9-b48c-71eb70e99ff9'	System	30 Sep 2020 11:03:21
User entered 'No (N)'	System	30 Sep 2020 11:03:21

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:15', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ab422e44-2375-45f9-b48c-71eb70e99ff9'	System	30 Sep 2020 11:03:21
User entered 'None (1)'	System	30 Sep 2020 11:03:21

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:18', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ab422e44-2375-45f9-b48c-71eb70e99ff9' User entered '30 Sep 2020 07:03'	System	30 Sep 2020 11:03:21
	System	30 Sep 2020 11:03:21

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 13:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 2'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:01:59', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f60d3e37-1f8b-4a3f-994e-526564c60ef3' User entered 'None (1)'	System	01 Oct 2020 10:02:16
	System	01 Oct 2020 10:02:16

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f60d3e37-1f8b-4a3f-994e-526564c60ef3' User entered 'No (N)'	System	01 Oct 2020 10:02:16
	System	01 Oct 2020 10:02:16

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:04', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f60d3e37-1f8b-4a3f-994e-526564c60ef3' User entered 'No (N)'	System	01 Oct 2020 10:02:16
	System	01 Oct 2020 10:02:16

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:07', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f60d3e37-1f8b-4a3f-994e-526564c60ef3' User entered 'None (1)'	System	01 Oct 2020 10:02:16
	System	01 Oct 2020 10:02:16

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:12', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f60d3e37-1f8b-4a3f-994e-526564c60ef3' User entered '01 Oct 2020 06:02'	System	01 Oct 2020 10:02:16
	System	01 Oct 2020 10:02:16

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 3'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T05:59:58', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fe0ce4f1-9bdb-46d6-b38c-f2d44e72fa83'	System	02 Oct 2020 10:00:19
User entered 'None (1)'	System	02 Oct 2020 10:00:19

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:02', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fe0ce4f1-9bdb-46d6-b38c-f2d44e72fa83'	System	02 Oct 2020 10:00:19
User entered 'No (N)'	System	02 Oct 2020 10:00:19

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:09', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fe0ce4f1-9bdb-46d6-b38c-f2d44e72fa83' User entered 'No (N)'	System	02 Oct 2020 10:00:19
	System	02 Oct 2020 10:00:19

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:12', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fe0ce4f1-9bdb-46d6-b38c-f2d44e72fa83'	System	02 Oct 2020 10:00:19
User entered 'None (1)'	System	02 Oct 2020 10:00:19

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:14', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fe0ce4f1-9bdb-46d6-b38c-f2d44e72fa83' User entered '02 Oct 2020 06:00'	System	02 Oct 2020 10:00:19
	System	02 Oct 2020 10:00:19

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 4'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:15', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fea6bcb9-27f2-49f6-a542-ecf29215d8ce' User entered 'None (1)'	System	03 Oct 2020 07:38:35
	System	03 Oct 2020 07:38:35

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:18', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fea6bcb9-27f2-49f6-a542-ecf29215d8ce'	System	03 Oct 2020 07:38:35
User entered 'No (N)'	System	03 Oct 2020 07:38:35

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:24', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fea6bcb9-27f2-49f6-a542-ecf29215d8ce' User entered 'No (N)'	System	03 Oct 2020 07:38:35
	System	03 Oct 2020 07:38:35

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:27', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fea6bcb9-27f2-49f6-a542-ecf29215d8ce' User entered 'None (1)'	System	03 Oct 2020 07:38:35
	System	03 Oct 2020 07:38:35

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:30', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'fea6bcb9-27f2-49f6-a542-ecf29215d8ce' User entered '03 Oct 2020 03:38'	System	03 Oct 2020 07:38:35
	System	03 Oct 2020 07:38:35

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 5'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T05:59:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '895ea8a5-0153-4eba-bd5e-9c76e495787f' User entered 'None (1)'	System	04 Oct 2020 10:00:13
	System	04 Oct 2020 10:00:13

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T05:59:58', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '895ea8a5-0153-4eba-bd5e-9c76e495787f' User entered 'No (N)'	System	04 Oct 2020 10:00:13
	System	04 Oct 2020 10:00:13

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '895ea8a5-0153-4eba-bd5e-9c76e495787f' User entered 'No (N)'	System	04 Oct 2020 10:00:13
	System	04 Oct 2020 10:00:13

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:04', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '895ea8a5-0153-4eba-bd5e-9c76e495787f' User entered 'None (1)'	System	04 Oct 2020 10:00:13
	System	04 Oct 2020 10:00:13

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:07', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '895ea8a5-0153-4eba-bd5e-9c76e495787f' User entered '04 Oct 2020 06:00'	System	04 Oct 2020 10:00:13
	System	04 Oct 2020 10:00:13

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 6'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:55:58', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1afd73df-d2e3-451d-a536-b37076aef82e' User entered 'None (1)'	System	05 Oct 2020 09:56:14
	System	05 Oct 2020 09:56:14

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:04', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1afd73df-d2e3-451d-a536-b37076aef82e' User entered 'No (N)'	System	05 Oct 2020 09:56:14
	System	05 Oct 2020 09:56:14

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:06', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1afd73df-d2e3-451d-a536-b37076aef82e' User entered 'No (N)'	System	05 Oct 2020 09:56:14
	System	05 Oct 2020 09:56:14

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:09', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1afd73df-d2e3-451d-a536-b37076aef82e' User entered 'None (1)'	System	05 Oct 2020 09:56:14
	System	05 Oct 2020 09:56:14

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:12', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1afd73df-d2e3-451d-a536-b37076aef82e' User entered '05 Oct 2020 05:56'	System	05 Oct 2020 09:56:14
	System	05 Oct 2020 09:56:14

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 7'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:34', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '593cfff2-b4b0-4c71-a17c-039973d374e5'	System	06 Oct 2020 11:14:48
User entered 'None (1)'	System	06 Oct 2020 11:14:48

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:36', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '593cff2-b4b0-4c71-a17c-039973d374e5'	System	06 Oct 2020 11:14:48
User entered 'No (N)'	System	06 Oct 2020 11:14:48

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:40', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '593cff2-b4b0-4c71-a17c-039973d374e5' User entered 'No (N)'	System	06 Oct 2020 11:14:48
	System	06 Oct 2020 11:14:48

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:43', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '593cfff2-b4b0-4c71-a17c-039973d374e5' User entered 'None (1)'	System	06 Oct 2020 11:14:48
	System	06 Oct 2020 11:14:48

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:46', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '593cff2-b4b0-4c71-a17c-039973d374e5' User entered '06 Oct 2020 07:14'	System	06 Oct 2020 11:14:48
	System	06 Oct 2020 11:14:48

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:37:59', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1a991c95-43e3-4dbd-9c9e-e3137880c8f2' User entered 'None (0)'	System	29 Sep 2020 13:38:51
	System	29 Sep 2020 13:38:51

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:38:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1a991c95-43e3-4dbd-9c9e-e3137880c8f2' User entered 'None (0)'	System	29 Sep 2020 13:38:51
	System	29 Sep 2020 13:38:51

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:38:05', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1a991c95-43e3-4dbd-9c9e-e3137880c8f2' User entered 'None (0)'	System	29 Sep 2020 13:38:51
	System	29 Sep 2020 13:38:51

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:38:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1a991c95-43e3-4dbd-9c9e-e3137880c8f2' User entered 'None (0)'	System	29 Sep 2020 13:38:51
	System	29 Sep 2020 13:38:51

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:38:14', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1a991c95-43e3-4dbd-9c9e-e3137880c8f2' User entered 'None (0)'	System	29 Sep 2020 13:38:51
	System	29 Sep 2020 13:38:51

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:38:16', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1a991c95-43e3-4dbd-9c9e-e3137880c8f2' User entered 'None (0)'	System	29 Sep 2020 13:38:51
	System	29 Sep 2020 13:38:51

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:38:23', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1a991c95-43e3-4dbd-9c9e-e3137880c8f2' User entered 'No (N)'	System	29 Sep 2020 13:38:51
	System	29 Sep 2020 13:38:51

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-29T09:38:25', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1a991c95-43e3-4dbd-9c9e-e3137880c8f2' User entered '29 Sep 2020 09:38'	System	29 Sep 2020 13:38:51
	System	29 Sep 2020 13:38:51

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 09:35'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 12:05'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:23', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a347fec6-0abb-42eb-bf0c-a0211a4b0069' User entered 'None (0)'	System	30 Sep 2020 11:03:43
	System	30 Sep 2020 11:03:43

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:25', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a347fec6-0abb-42eb-bf0c-a0211a4b0069' User entered 'None (0)'	System	30 Sep 2020 11:03:43
	System	30 Sep 2020 11:03:43

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:28', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a347fec6-0abb-42eb-bf0c-a0211a4b0069' User entered 'None (0)'	System	30 Sep 2020 11:03:43
	System	30 Sep 2020 11:03:43

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:30', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a347fec6-0abb-42eb-bf0c-a0211a4b0069' User entered 'None (0)'	System	30 Sep 2020 11:03:43
	System	30 Sep 2020 11:03:43

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:33', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a347fec6-0abb-42eb-bf0c-a0211a4b0069' User entered 'None (0)'	System	30 Sep 2020 11:03:43
	System	30 Sep 2020 11:03:43

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:35', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a347fec6-0abb-42eb-bf0c-a0211a4b0069' User entered 'None (0)'	System	30 Sep 2020 11:03:43
	System	30 Sep 2020 11:03:43

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:39', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a347fec6-0abb-42eb-bf0c-a0211a4b0069' User entered 'No (N)'	System	30 Sep 2020 11:03:43
	System	30 Sep 2020 11:03:43

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-09-30T07:03:41', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a347fec6-0abb-42eb-bf0c-a0211a4b0069' User entered '30 Sep 2020 07:03'	System	30 Sep 2020 11:03:43
	System	30 Sep 2020 11:03:43

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '29 Sep 2020 13:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 2'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:17', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '67d88727-a693-4859-914b-cef004f87245' User entered 'None (0)'	System	01 Oct 2020 10:02:38
	System	01 Oct 2020 10:02:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:19', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '67d88727-a693-4859-914b-cef004f87245' User entered 'None (0)'	System	01 Oct 2020 10:02:38
	System	01 Oct 2020 10:02:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:21', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '67d88727-a693-4859-914b-cef004f87245' User entered 'None (0)'	System	01 Oct 2020 10:02:38
	System	01 Oct 2020 10:02:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:25', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '67d88727-a693-4859-914b-cef004f87245' User entered 'None (0)'	System	01 Oct 2020 10:02:38
	System	01 Oct 2020 10:02:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:27', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '67d88727-a693-4859-914b-cef004f87245' User entered 'None (0)'	System	01 Oct 2020 10:02:38
	System	01 Oct 2020 10:02:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:28', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '67d88727-a693-4859-914b-cef004f87245' User entered 'None (0)'	System	01 Oct 2020 10:02:38
	System	01 Oct 2020 10:02:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:31', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '67d88727-a693-4859-914b-cef004f87245' User entered 'No (N)'	System	01 Oct 2020 10:02:38
	System	01 Oct 2020 10:02:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-01T06:02:35', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '67d88727-a693-4859-914b-cef004f87245' User entered '01 Oct 2020 06:02'	System	01 Oct 2020 10:02:38
	System	01 Oct 2020 10:02:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 3'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:18', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b45b73ba-c540-4c2f-8279-b7e082644a03' User entered 'None (0)'	System	02 Oct 2020 10:00:38
	System	02 Oct 2020 10:00:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:20', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b45b73ba-c540-4c2f-8279-b7e082644a03' User entered 'None (0)'	System	02 Oct 2020 10:00:38
	System	02 Oct 2020 10:00:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:22', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b45b73ba-c540-4c2f-8279-b7e082644a03' User entered 'None (0)'	System	02 Oct 2020 10:00:38
	System	02 Oct 2020 10:00:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:28', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b45b73ba-c540-4c2f-8279-b7e082644a03' User entered 'None (0)'	System	02 Oct 2020 10:00:38
	System	02 Oct 2020 10:00:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:30', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b45b73ba-c540-4c2f-8279-b7e082644a03' User entered 'None (0)'	System	02 Oct 2020 10:00:38
	System	02 Oct 2020 10:00:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:32', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b45b73ba-c540-4c2f-8279-b7e082644a03' User entered 'None (0)'	System	02 Oct 2020 10:00:38
	System	02 Oct 2020 10:00:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:34', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b45b73ba-c540-4c2f-8279-b7e082644a03'	System	02 Oct 2020 10:00:38
User entered 'No (N)'	System	02 Oct 2020 10:00:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-02T06:00:37', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b45b73ba-c540-4c2f-8279-b7e082644a03' User entered '02 Oct 2020 06:00'	System	02 Oct 2020 10:00:38
	System	02 Oct 2020 10:00:38

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 4'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:34', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '0acdc47d-b210-4efc-9477-57b8879078b7' User entered 'None (0)'	System	03 Oct 2020 07:38:55
	System	03 Oct 2020 07:38:55

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:36', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '0acdc47d-b210-4efc-9477-57b8879078b7' User entered 'None (0)'	System	03 Oct 2020 07:38:55
	System	03 Oct 2020 07:38:55

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:39', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '0acdc47d-b210-4efc-9477-57b8879078b7' User entered 'None (0)'	System	03 Oct 2020 07:38:55
	System	03 Oct 2020 07:38:55

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:41', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '0acdc47d-b210-4efc-9477-57b8879078b7' User entered 'None (0)'	System	03 Oct 2020 07:38:55
	System	03 Oct 2020 07:38:55

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:43', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '0acdc47d-b210-4efc-9477-57b8879078b7' User entered 'None (0)'	System	03 Oct 2020 07:38:55
	System	03 Oct 2020 07:38:55

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:45', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '0acdc47d-b210-4efc-9477-57b8879078b7' User entered 'None (0)'	System	03 Oct 2020 07:38:55
	System	03 Oct 2020 07:38:55

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:49', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '0acdc47d-b210-4efc-9477-57b8879078b7' User entered 'No (N)'	System	03 Oct 2020 07:38:55
	System	03 Oct 2020 07:38:55

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-03T03:38:51', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '0acdc47d-b210-4efc-9477-57b8879078b7' User entered '03 Oct 2020 03:38'	System	03 Oct 2020 07:38:55
	System	03 Oct 2020 07:38:55

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 5'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '540a76c0-8a57-4517-8773-ca73f33ddfcc' User entered 'None (0)'	System	04 Oct 2020 10:00:25
	System	04 Oct 2020 10:00:25

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:12', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '540a76c0-8a57-4517-8773-ca73f33ddfcc' User entered 'None (0)'	System	04 Oct 2020 10:00:25
	System	04 Oct 2020 10:00:25

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:14', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '540a76c0-8a57-4517-8773-ca73f33ddfcc' User entered 'None (0)'	System	04 Oct 2020 10:00:25
	System	04 Oct 2020 10:00:25

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:15', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '540a76c0-8a57-4517-8773-ca73f33ddfcc' User entered 'None (0)'	System	04 Oct 2020 10:00:25
	System	04 Oct 2020 10:00:25

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:17', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '540a76c0-8a57-4517-8773-ca73f33ddfcc' User entered 'None (0)'	System	04 Oct 2020 10:00:25
	System	04 Oct 2020 10:00:25

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:18', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '540a76c0-8a57-4517-8773-ca73f33ddfcc' User entered 'None (0)'	System	04 Oct 2020 10:00:25
	System	04 Oct 2020 10:00:25

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:21', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '540a76c0-8a57-4517-8773-ca73f33ddfcc' User entered 'No (N)'	System	04 Oct 2020 10:00:25
	System	04 Oct 2020 10:00:25

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-04T06:00:23', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '540a76c0-8a57-4517-8773-ca73f33ddfcc' User entered '04 Oct 2020 06:00'	System	04 Oct 2020 10:00:25
	System	04 Oct 2020 10:00:25

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 6'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:16', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2190892e-9e38-466e-b89e-0db9c589b226' User entered 'None (0)'	System	05 Oct 2020 09:56:33
	System	05 Oct 2020 09:56:33

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:18', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2190892e-9e38-466e-b89e-0db9c589b226' User entered 'None (0)'	System	05 Oct 2020 09:56:33
	System	05 Oct 2020 09:56:33

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:20', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2190892e-9e38-466e-b89e-0db9c589b226' User entered 'None (0)'	System	05 Oct 2020 09:56:33
	System	05 Oct 2020 09:56:33

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:22', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2190892e-9e38-466e-b89e-0db9c589b226' User entered 'None (0)'	System	05 Oct 2020 09:56:33
	System	05 Oct 2020 09:56:33

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:23', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2190892e-9e38-466e-b89e-0db9c589b226' User entered 'None (0)'	System	05 Oct 2020 09:56:33
	System	05 Oct 2020 09:56:33

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:25', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2190892e-9e38-466e-b89e-0db9c589b226' User entered 'None (0)'	System	05 Oct 2020 09:56:33
	System	05 Oct 2020 09:56:33

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:27', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2190892e-9e38-466e-b89e-0db9c589b226' User entered 'No (N)'	System	05 Oct 2020 09:56:33
	System	05 Oct 2020 09:56:33

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-05T05:56:32', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2190892e-9e38-466e-b89e-0db9c589b226' User entered '05 Oct 2020 05:56'	System	05 Oct 2020 09:56:33
	System	05 Oct 2020 09:56:33

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	29 Sep 2020 13:17:00
User entered 'Day 7'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:49', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '510b63b3-cf58-47aa-8d40-af34dc335679' User entered 'None (0)'	System	06 Oct 2020 11:15:12
	System	06 Oct 2020 11:15:12

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:51', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '510b63b3-cf58-47aa-8d40-af34dc335679' User entered 'None (0)'	System	06 Oct 2020 11:15:12
	System	06 Oct 2020 11:15:12

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:52', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '510b63b3-cf58-47aa-8d40-af34dc335679' User entered 'None (0)'	System	06 Oct 2020 11:15:12
	System	06 Oct 2020 11:15:12

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '510b63b3-cf58-47aa-8d40-af34dc335679' User entered 'None (0)'	System	06 Oct 2020 11:15:12
	System	06 Oct 2020 11:15:12

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:56', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '510b63b3-cf58-47aa-8d40-af34dc335679' User entered 'None (0)'	System	06 Oct 2020 11:15:12
	System	06 Oct 2020 11:15:12

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:14:58', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '510b63b3-cf58-47aa-8d40-af34dc335679' User entered 'None (0)'	System	06 Oct 2020 11:15:12
	System	06 Oct 2020 11:15:12

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:15:06', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '510b63b3-cf58-47aa-8d40-af34dc335679' User entered 'No (N)'	System	06 Oct 2020 11:15:12
	System	06 Oct 2020 11:15:12

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-10-06T07:15:09', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '510b63b3-cf58-47aa-8d40-af34dc335679' User entered '06 Oct 2020 07:15'	System	06 Oct 2020 11:15:12
	System	06 Oct 2020 11:15:12

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 13:17:00

US3662032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:19:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 13:17:00

US3662032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	09 Oct 2020 19:19:52

US3662032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 19:19:52

US3662032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	09 Oct 2020 19:19:52

US3662032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Participant is out of the country. Texted participant on numerous times and got no response'	(b) (4) Brenda Miller (b) (4)	09 Oct 2020 19:19:52

US3662032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Oct 2020 13:09:33

US3662032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered 'I'	System	16 Oct 2020 13:09:33

US3662032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Oct 2020 13:09:50

US3662032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '13 Oct 2020'	Brenda Miller (b) (4)	16 Oct 2020 13:09:50

US3662032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	16 Oct 2020 13:09:50

US3662032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	16 Oct 2020 13:09:50

US3662032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	16 Oct 2020 13:10:28

US3662032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered 'I'	System	16 Oct 2020 13:10:28

US3662032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Oct 2020 18:15:51

US3662032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '20 Oct 2020'	Brenda Miller (b) (4)	23 Oct 2020 18:15:51

US3662032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	23 Oct 2020 18:15:51

US3662032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	23 Oct 2020 18:15:51

US3662032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Oct 2020 18:16:20

US3662032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered 'I'	System	23 Oct 2020 18:16:20

US3662032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Nov 2020 18:42:09

US3662032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '27 Oct 2020'	(b) (4) Brenda Miller (b) (4)	02 Nov 2020 18:42:09

US3662032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[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 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4)	02 Nov 2020 18:42:09

US3662032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'VISIT3'	System	02 Nov 2020 18:42:09

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '27 Oct 2020'	(b) (4) Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:10'	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '27 Oct 2020 08:10'	System	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.3' F	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '68'	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'bpm'	System	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '16'	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'breaths/min'	System	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '138'	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '88'	Brenda Miller (b) (4)	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'mmHg'	System	02 Nov 2020 18:43:01

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53

US3662032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53

US3662032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	02 Nov 2020 18:43:11

US3662032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	02 Nov 2020 18:43:11

US3662032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	02 Nov 2020 18:43:28

US3662032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '27 Oct 2020'	Brenda Miller (b) (4)	02 Nov 2020 18:43:28

US3662032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:15'	Brenda Miller (b) (4)	02 Nov 2020 18:43:28

US3662032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered '27 Oct 2020 08:15'	System	02 Nov 2020 18:43:28

US3662032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:17:08

US3662032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:53
User entered 'I'	System	27 Oct 2020 12:17:08

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 64'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-04T17:59:17', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'cedaa60d-3545-487a-a3b7-58cc9637e476' User entered 'No (N)'	System	04 Nov 2020 22:59:26
	System	04 Nov 2020 22:59:26

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-04T17:59:19', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'cedaa60d-3545-487a-a3b7-58cc9637e476' User entered 'No (N)'	System	04 Nov 2020 22:59:26
	System	04 Nov 2020 22:59:26

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-04T17:59:24', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'cedaa60d-3545-487a-a3b7-58cc9637e476' User entered '04 Nov 2020 17:59:24'	System	04 Nov 2020 22:59:26
	System	04 Nov 2020 22:59:26

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 71'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-08T13:29:49', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e6bb6e75-4f53-4531-83f5-83512d0f5007'	System	08 Nov 2020 18:29:57
User entered 'No (N)'	System	08 Nov 2020 18:29:57

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-08T13:29:52', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e6bb6e75-4f53-4531-83f5-83512d0f5007'	System	08 Nov 2020 18:29:57
User entered 'No (N)'	System	08 Nov 2020 18:29:57

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-08T13:29:56', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e6bb6e75-4f53-4531-83f5-83512d0f5007' User entered '08 Nov 2020 13:29:56'	System	08 Nov 2020 18:29:57
	System	08 Nov 2020 18:29:57

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered 'Day 78'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-18T17:59:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '209e036a-a4f3-4339-81cc-31d5f7662332' User entered 'No (N)'	System	18 Nov 2020 22:59:20
	System	18 Nov 2020 22:59:20

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-18T17:59:14', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '209e036a-a4f3-4339-81cc-31d5f7662332'	System	18 Nov 2020 22:59:20
User entered 'No (N)'	System	18 Nov 2020 22:59:20

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-11-18T17:59:18', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '209e036a-a4f3-4339-81cc-31d5f7662332' User entered '18 Nov 2020 17:59:18'	System	18 Nov 2020 22:59:20
	System	18 Nov 2020 22:59:20

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 14:13:24

US3662032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:37:56
Data entry locked.	System	01 Sep 2020 14:13:24
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 14:13:24

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-03T01:54:59', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f2671cc2-b17d-409a-93df-e6de68a3bb9a' User entered 'No (N)'	System	03 Dec 2020 06:55:09
	System	03 Dec 2020 06:55:09

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-03T01:55:03', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f2671cc2-b17d-409a-93df-e6de68a3bb9a' User entered 'No (N)'	System	03 Dec 2020 06:55:09
	System	03 Dec 2020 06:55:09

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-03T01:55:07', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'f2671cc2-b17d-409a-93df-e6de68a3bb9a' User entered '03 Dec 2020 01:55:07'	System	03 Dec 2020 06:55:09
	System	03 Dec 2020 06:55:09

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-13T17:59:11', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a027dc4d-69b8-43c9-a963-99cfe7cbd48f' User entered 'No (N)'	System	14 Dec 2020 15:06:44
	System	14 Dec 2020 15:06:44

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-13T17:59:14', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a027dc4d-69b8-43c9-a963-99cfe7cbd48f' User entered 'No (N)'	System	14 Dec 2020 15:06:44

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-13T17:59:19', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a027dc4d-69b8-43c9-a963-99cfe7cbd48f' User entered '13 Dec 2020 17:59:19'	System	14 Dec 2020 15:06:44
	System	14 Dec 2020 15:06:44

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-19T12:00:16', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7b019c78-bded-48ac-bf41-bc9caf0f5789'	System	19 Dec 2020 17:00:27
User entered 'No (N)'	System	19 Dec 2020 17:00:27

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-19T12:00:19', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7b019c78-bded-48ac-bf41-bc9caf0f5789'	System	19 Dec 2020 17:00:27
User entered 'No (N)'	System	19 Dec 2020 17:00:27

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-19T12:00:23', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '7b019c78-bded-48ac-bf41-bc9caf0f5789' User entered '19 Dec 2020 12:00:23'	System	19 Dec 2020 17:00:27
	System	19 Dec 2020 17:00:27

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-24T04:24:04', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '30d91dcd-f82b-4852-aa7d-e19b1c643ae9' User entered 'No (N)'	System	24 Dec 2020 09:24:15
	System	24 Dec 2020 09:24:15

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-24T04:24:09', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '30d91dcd-f82b-4852-aa7d-e19b1c643ae9' User entered 'No (N)'	System	24 Dec 2020 09:24:15
	System	24 Dec 2020 09:24:15

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-24T04:24:13', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '30d91dcd-f82b-4852-aa7d-e19b1c643ae9' User entered '24 Dec 2020 04:24:13'	System	24 Dec 2020 09:24:15
	System	24 Dec 2020 09:24:15

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-31T01:17:41', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '935c8b4d-96b1-43f3-97be-5bbcd54ff00c'	System	31 Dec 2020 06:17:56
User entered 'No (N)'	System	31 Dec 2020 06:17:56

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-31T01:17:47', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '935c8b4d-96b1-43f3-97be-5bbcd54ff00c' User entered 'No (N)'	System	31 Dec 2020 06:17:56
	System	31 Dec 2020 06:17:56

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2020-12-31T01:17:54', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '935c8b4d-96b1-43f3-97be-5bbcd54ff00c' User entered '31 Dec 2020 01:17:54'	System	31 Dec 2020 06:17:56
	System	31 Dec 2020 06:17:56

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-07T00:10:24', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '46c4bcba-3742-43a5-9dba-f9f355e66723' User entered 'No (N)'	System	07 Jan 2021 05:10:34
	System	07 Jan 2021 05:10:34

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-07T00:10:28', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '46c4bcba-3742-43a5-9dba-f9f355e66723' User entered 'No (N)'	System	07 Jan 2021 05:10:34

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-07T00:10:31', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '46c4bcba-3742-43a5-9dba-f9f355e66723' User entered '07 Jan 2021 00:10:31'	System	07 Jan 2021 05:10:34
	System	07 Jan 2021 05:10:34

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-14T00:03:41', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'aa2e2b20-bcf5-49a5-8c6f-48cf918990f9' User entered 'No (N)'	System	14 Jan 2021 05:03:58
	System	14 Jan 2021 05:03:58

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-14T00:03:44', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'aa2e2b20-bcf5-49a5-8c6f-48cf918990f9' User entered 'No (N)'	System	14 Jan 2021 05:03:58
	System	14 Jan 2021 05:03:58

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-14T00:03:53', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'aa2e2b20-bcf5-49a5-8c6f-48cf918990f9' User entered '14 Jan 2021 00:03:53'	System	14 Jan 2021 05:03:58
	System	14 Jan 2021 05:03:58

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-23T12:00:29', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4148d564-53d4-436f-bc3c-a17b13c7ce86' User entered 'No (N)'	System	25 Jan 2021 15:40:43
	System	25 Jan 2021 15:40:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-23T12:00:31', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4148d564-53d4-436f-bc3c-a17b13c7ce86'	System	25 Jan 2021 15:40:43
User entered 'No (N)'	System	25 Jan 2021 15:40:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-23T12:00:34', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '4148d564-53d4-436f-bc3c-a17b13c7ce86' User entered '23 Jan 2021 12:00:34'	System	25 Jan 2021 15:40:43
	System	25 Jan 2021 15:40:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-28T05:58:37', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1af6c56e-0c48-4246-8020-870347140e5e' User entered 'No (N)'	System	28 Jan 2021 09:58:54
	System	28 Jan 2021 09:58:54

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-28T05:58:44', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1af6c56e-0c48-4246-8020-870347140e5e'	System	28 Jan 2021 09:58:54
User entered 'No (N)'	System	28 Jan 2021 09:58:54

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-01-28T05:58:51', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1af6c56e-0c48-4246-8020-870347140e5e' User entered '28 Jan 2021 05:58:51'	System	28 Jan 2021 09:58:54
	System	28 Jan 2021 09:58:54

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-06T12:00:16', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '93488f9f-a309-421b-a21f-5d0ac9521742'	System	06 Feb 2021 16:00:29
User entered 'No (N)'	System	06 Feb 2021 16:00:29

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-06T12:00:20', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '93488f9f-a309-421b-a21f-5d0ac9521742'	System	06 Feb 2021 16:00:29
User entered 'No (N)'	System	06 Feb 2021 16:00:29

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-06T12:00:25', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '93488f9f-a309-421b-a21f-5d0ac9521742' User entered '06 Feb 2021 12:00:25'	System	06 Feb 2021 16:00:29
	System	06 Feb 2021 16:00:29

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-11T02:05:22', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '371646fe-5d2b-484c-b96d-cf046c353b74' User entered 'No (N)'	System	11 Feb 2021 06:05:39
	System	11 Feb 2021 06:05:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-11T02:05:27', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '371646fe-5d2b-484c-b96d-cf046c353b74'	System	11 Feb 2021 06:05:39
User entered 'No (N)'	System	11 Feb 2021 06:05:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-11T02:05:32', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '371646fe-5d2b-484c-b96d-cf046c353b74' User entered '11 Feb 2021 02:05:32'	System	11 Feb 2021 06:05:39
	System	11 Feb 2021 06:05:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-18T07:05:55', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ddb43a0e-33c2-45ac-967d-d84a31f6031c' User entered 'No (N)'	System	18 Feb 2021 12:06:03
	System	18 Feb 2021 12:06:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-18T07:05:58', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ddb43a0e-33c2-45ac-967d-d84a31f6031c' User entered 'No (N)'	System	18 Feb 2021 12:06:03
	System	18 Feb 2021 12:06:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-18T07:06:01', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'ddb43a0e-33c2-45ac-967d-d84a31f6031c' User entered '18 Feb 2021 07:06:01'	System	18 Feb 2021 12:06:03
	System	18 Feb 2021 12:06:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:08-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered 'Yes (Y)'	System	25 Feb 2021 12:06:39
	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:14-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c'	System	25 Feb 2021 12:06:39
User entered 'No (N)'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:23-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered 'Yes (Y)'	System	25 Feb 2021 12:06:39
	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c'	System	25 Feb 2021 12:06:39
User entered '1'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '1'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '1'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '1'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39
	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '1'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39
	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39
	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '1'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39
	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39
	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:05:56-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '0'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Please 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:06:03-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c'	System	25 Feb 2021 12:06:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:06:11-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c'	System	25 Feb 2021 12:06:39
User entered 'Yes (Y)'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Please 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:06:14-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c'	System	25 Feb 2021 12:06:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-02-25T07:06:20-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e3b51dfa-4a76-467e-bfbb-0c7c6ec06c1c' User entered '25 Feb 2021 12:06:20'	System	25 Feb 2021 12:06:39
	System	25 Feb 2021 12:06:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-04T07:58:19-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '36688680-6d10-48d1-9390-f31765fe5937'	System	04 Mar 2021 12:59:03
User entered 'Yes (Y)'	System	04 Mar 2021 12:59:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-04T07:58:23-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '36688680-6d10-48d1-9390-f31765fe5937'	System	04 Mar 2021 12:59:03
User entered 'No (N)'	System	04 Mar 2021 12:59:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-04T07:58:38-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '36688680-6d10-48d1-9390-f31765fe5937'	System	04 Mar 2021 12:59:03
User entered 'No (N)'	System	04 Mar 2021 12:59:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-04T07:58:42-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '36688680-6d10-48d1-9390-f31765fe5937'	System	04 Mar 2021 12:59:03
User entered 'Yes (Y)'	System	04 Mar 2021 12:59:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Please 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-04T07:58:47-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '36688680-6d10-48d1-9390-f31765fe5937'	System	04 Mar 2021 12:59:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Mar 2021 12:59:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-04T07:58:51-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '36688680-6d10-48d1-9390-f31765fe5937' User entered '04 Mar 2021 07:58:51'	System	04 Mar 2021 12:59:03
	System	04 Mar 2021 12:59:03

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-11T18:01:22-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1296cf05-8bf0-4475-a7e4-7b1b3b5477b3'	System	11 Mar 2021 23:06:26
User entered 'Yes (Y)'	System	11 Mar 2021 23:06:26

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-11T18:01:27-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1296cf05-8bf0-4475-a7e4-7b1b3b5477b3'	System	11 Mar 2021 23:06:26
User entered 'No (N)'	System	11 Mar 2021 23:06:26

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-11T18:01:31-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1296cf05-8bf0-4475-a7e4-7b1b3b5477b3'	System	11 Mar 2021 23:06:26
User entered 'No (N)'	System	11 Mar 2021 23:06:26

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-11T18:01:43-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1296cf05-8bf0-4475-a7e4-7b1b3b5477b3'	System	11 Mar 2021 23:06:26
User entered 'Yes (Y)'	System	11 Mar 2021 23:06:26

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Please 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-11T18:01:48-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1296cf05-8bf0-4475-a7e4-7b1b3b5477b3'	System	11 Mar 2021 23:06:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Mar 2021 23:06:26

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-11T18:01:51-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '1296cf05-8bf0-4475-a7e4-7b1b3b5477b3'	System	11 Mar 2021 23:06:26
User entered '11 Mar 2021 18:01:51'	System	11 Mar 2021 23:06:26

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-20T11:07:29-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a2781899-4a50-46f7-922d-b98948eb1f8b'	System	20 Mar 2021 15:07:37
User entered 'No (N)'	System	20 Mar 2021 15:07:37

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-20T11:07:31-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a2781899-4a50-46f7-922d-b98948eb1f8b'	System	20 Mar 2021 15:07:37
User entered 'No (N)'	System	20 Mar 2021 15:07:37

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-20T11:07:36-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a2781899-4a50-46f7-922d-b98948eb1f8b'	System	20 Mar 2021 15:07:37
User entered '20 Mar 2021 11:07:36'	System	20 Mar 2021 15:07:37

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-27T21:02:04-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '83da908e-7d8d-4566-b2df-1e730514e43a'	System	28 Mar 2021 01:03:39
User entered 'No (N)'	System	28 Mar 2021 01:03:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-27T21:02:07-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '83da908e-7d8d-4566-b2df-1e730514e43a' User entered 'No (N)'	System	28 Mar 2021 01:03:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-27T21:02:12-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '83da908e-7d8d-4566-b2df-1e730514e43a' User entered '27 Mar 2021 21:02:12'	System	28 Mar 2021 01:03:39
	System	28 Mar 2021 01:03:39

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-03T12:30:44-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2d0559a0-4e7e-48f1-982c-020e34cd47ba' User entered 'No (N)'	System	03 Apr 2021 16:31:08
	System	03 Apr 2021 16:31:08

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-03T12:30:47-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2d0559a0-4e7e-48f1-982c-020e34cd47ba' User entered 'No (N)'	System	03 Apr 2021 16:31:08

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-03T12:30:51-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '2d0559a0-4e7e-48f1-982c-020e34cd47ba' User entered '03 Apr 2021 12:30:51'	System	03 Apr 2021 16:31:08
	System	03 Apr 2021 16:31:08

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-10T12:08:29-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e4658dfe-9c72-4b98-8dad-9667b6ef1997'	System	10 Apr 2021 16:09:51
User entered 'Yes (Y)'	System	10 Apr 2021 16:09:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-10T12:08:33-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e4658dfe-9c72-4b98-8dad-9667b6ef1997'	System	10 Apr 2021 16:09:51
User entered 'No (N)'	System	10 Apr 2021 16:09:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-10T12:08:40-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e4658dfe-9c72-4b98-8dad-9667b6ef1997'	System	10 Apr 2021 16:09:51
User entered 'No (N)'	System	10 Apr 2021 16:09:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-10T12:08:56-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e4658dfe-9c72-4b98-8dad-9667b6ef1997'	System	10 Apr 2021 16:09:51
User entered 'Yes (Y)'	System	10 Apr 2021 16:09:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Please 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-10T12:09:00-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e4658dfe-9c72-4b98-8dad-9667b6ef1997'	System	10 Apr 2021 16:09:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Apr 2021 16:09:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-10T12:09:09-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'e4658dfe-9c72-4b98-8dad-9667b6ef1997'	System	10 Apr 2021 16:09:51
User entered '10 Apr 2021 12:09:09'	System	10 Apr 2021 16:09:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-17T12:29:15-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '6b0e4673-786e-4176-a4aa-4a6103ac3038'	System	17 Apr 2021 16:29:23
User entered 'No (N)'	System	17 Apr 2021 16:29:23

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-17T12:29:18-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '6b0e4673-786e-4176-a4aa-4a6103ac3038'	System	17 Apr 2021 16:29:23
User entered 'No (N)'	System	17 Apr 2021 16:29:23

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-17T12:29:20-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '6b0e4673-786e-4176-a4aa-4a6103ac3038'	System	17 Apr 2021 16:29:23
User entered '17 Apr 2021 12:29:20'	System	17 Apr 2021 16:29:23

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-24T12:28:39-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a41412db-b666-47b3-b5fa-2d93c892133f' User entered 'No (N)'	System	24 Apr 2021 16:28:51
	System	24 Apr 2021 16:28:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-24T12:28:41-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a41412db-b666-47b3-b5fa-2d93c892133f' User entered 'No (N)'	System	24 Apr 2021 16:28:51
	System	24 Apr 2021 16:28:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-04-24T12:28:44-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'a41412db-b666-47b3-b5fa-2d93c892133f' User entered '24 Apr 2021 12:28:44'	System	24 Apr 2021 16:28:51
	System	24 Apr 2021 16:28:51

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-05-01T12:28:11-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '3d5964de-dee2-4318-8f07-7f24bdf757be' User entered 'Yes (Y)'	System	01 May 2021 16:28:43
	System	01 May 2021 16:28:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

Have you been exposed to someone with 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-05-01T12:28:14-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '3d5964de-dee2-4318-8f07-7f24bdf757be'	System	01 May 2021 16:28:43
User entered 'No (N)'	System	01 May 2021 16:28:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-05-01T12:28:18-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '3d5964de-dee2-4318-8f07-7f24bdf757be'	System	01 May 2021 16:28:43
User entered 'No (N)'	System	01 May 2021 16:28:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-05-01T12:28:23-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '3d5964de-dee2-4318-8f07-7f24bdf757be' User entered 'Yes (Y)'	System	01 May 2021 16:28:43
	System	01 May 2021 16:28:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Please 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 (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-05-01T12:28:28-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '3d5964de-dee2-4318-8f07-7f24bdf757be'	System	01 May 2021 16:28:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 May 2021 16:28:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-05-01T12:28:32-04:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: '3d5964de-dee2-4318-8f07-7f24bdf757be' User entered '01 May 2021 12:28:32'	System	01 May 2021 16:28:43
	System	01 May 2021 16:28:43

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:31:07

US3662032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:19:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:31:07
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:31:07

US3662032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:19:44

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 01:42:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-04T07:58:03-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b8559bc1-8bd0-440d-b46e-17e01a94eb8f' User entered 'No (N)'	System	04 Mar 2021 12:58:45
	System	04 Mar 2021 12:58:45

US3662032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:19:44

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:42:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A44C1DE5-1D72-47EE-910A-2930C59E16EC)', Time: '2021-03-04T07:58:13-05:00', User OID: 'PatientReportedOutcome (US3662032)', ODM File OID: 'b8559bc1-8bd0-440d-b46e-17e01a94eb8f' User entered '04 Mar 2021 07:58:13'	System	04 Mar 2021 12:58:45
	System	04 Mar 2021 12:58:45

US3662032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	24 Nov 2020 19:52:21

US3662032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '23 Nov 2020'	Angela Snyder (b) (4)	24 Nov 2020 19:52:21

US3662032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	24 Nov 2020 19:52:21

US3662032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Angela Snyder (b) (4)	24 Nov 2020 19:52:21

US3662032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	24 Nov 2020 19:52:27

US3662032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:09:22
User entered 'I'	System	24 Nov 2020 19:52:27

US3662032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	29 Dec 2020 17:01:02

US3662032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '28 Dec 2020'	Brenda Miller (b) (4)	29 Dec 2020 17:01:02

US3662032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4)	29 Dec 2020 17:01:02

US3662032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Brenda Miller (b) (4)	29 Dec 2020 17:01:02

US3662032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	29 Dec 2020 17:01:12

US3662032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User entered 'I'	System	29 Dec 2020 17:01:12

US3662032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Jan 2021 17:53:19

US3662032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '26 Jan 2021'	Angela Snyder (b) (4)	29 Jan 2021 17:53:19

US3662032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	29 Jan 2021 17:53:19

US3662032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Angela Snyder (b) (4)	29 Jan 2021 17:53:19

US3662032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Jan 2021 17:53:26

US3662032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User entered 'I'	System	29 Jan 2021 17:53:26

US3662032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Feb 2021 15:23:38

US3662032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '25 Feb 2021'	Angela Snyder (b) (4)	26 Feb 2021 15:23:38

US3662032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	26 Feb 2021 15:23:38

US3662032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	26 Feb 2021 15:23:38

US3662032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Feb 2021 15:23:43

US3662032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:46:11
User entered 'I'	System	26 Feb 2021 15:23:43

US3662032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:29:01
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '18 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:29:01
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	25 Mar 2021 18:29:01
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User entered 'VISIT4'	System	25 Mar 2021 18:29:01

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '18 Mar 2021'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '07:09'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User entered '18 Mar 2021 07:09'	System	30 Mar 2021 11:26:43

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '97.7' F	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Other (Other)'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'infrared thermometer'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '83'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User entered 'bpm'	System	30 Mar 2021 11:26:43

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '16'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User entered 'breaths/min'	System	30 Mar 2021 11:26:43

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '140'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User entered 'mmHg'	System	30 Mar 2021 11:26:43

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '92'	Angela Snyder (b) (4)	30 Mar 2021 11:26:43
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User entered 'mmHg'	System	30 Mar 2021 11:26:43

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44

US3662032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44

US3662032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:29:11
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '18 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:29:11
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:29:32
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '18 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:29:32
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '07:16'	Angela Snyder (b) (4)	25 Mar 2021 18:29:32
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User entered '18 Mar 2021 07:16'	System	25 Mar 2021 18:29:32

US3662032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:29:38
	(b) (4)	

US3662032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:44
User entered '1'	System	25 Mar 2021 18:29:38

US3662032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Apr 2021 18:50:51
	(b) (4)	

US3662032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '26 Apr 2021'	Angela Snyder (b) (4)	26 Apr 2021 18:50:51
	(b) (4)	

US3662032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	26 Apr 2021 18:50:51

US3662032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	26 Apr 2021 18:50:51
	(b) (4)	

US3662032

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Apr 2021 18:50:57
	(b) (4)	

US3662032

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 18:50:57

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:26:32

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '09:18'	Angela Snyder (b) (4)	25 Feb 2021 18:26:32

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:43
User entered '24 Feb 2021 09:18'	System	25 Feb 2021 18:26:32

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Angela Snyder (b) (4)	25 Feb 2021 18:26:32

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:43
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:26:32

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Day 1 (Day 1)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '19 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User entered '%'	System	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:35:11
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:27:43
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:27:43

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:19:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:35:11
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:27:43
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Day 2 (Day 2)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '20 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User entered '%'	System	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:35:26
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:28:30
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:28:30

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:19:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:35:26
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:28:30
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Day 3 (Day 3)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '21 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User entered '%'	System	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:35:41
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:29:16
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:16

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:19:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:35:41
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:29:16
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Day 4 (Day 4)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '22 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User entered '%'	System	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:36:00
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:29:53
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:29:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:19:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:36:00
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:29:53
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Day 5 (Day 5)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '23 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User entered '%'	System	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered missing code ND - Not Done.	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:36:16
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:30:38
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:30:38

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:19:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:36:16
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:30:38
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Day 6 (Day 6)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '96'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User entered '%'	System	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '98.0' F	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:34:45
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:31:25
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Moderate (Moderate)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (None)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:19:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:45:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Mar 2021 19:34:45
User entered 'None (None)'	(b) (4)	
	Angela Snyder (b) (4)	25 Feb 2021 18:31:25
	(b) (4)	

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[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 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[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 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[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 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:15
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:15
User entered '0'	System	03 Mar 2021 19:48:47

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:19:44

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:22
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	03 Mar 2021 13:45:25

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:33:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '09:18'	Angela Snyder (b) (4)	25 Feb 2021 18:33:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:33
User entered '24 Feb 2021 09:18'	System	25 Feb 2021 18:33:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Angela Snyder (b) (4)	25 Feb 2021 18:33:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:19:44

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:33:53

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[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 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[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 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[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 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'UC Health'	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:47
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:34:23

US3662032

Folder: Covid-19 Assessment 24 Feb 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:19:44

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:46:47
User entered '0'	System	25 Feb 2021 18:34:23

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:19:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User accepted default value 'Day 3 (Day 3)'	Michelle Saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:19:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:19:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:19:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User accepted default value 'Day 5 (Day 5)'	Michelle Saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:19:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:19:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:19:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User accepted default value 'Day 7 (Day 7)'	Michelle Saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:19:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:19:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:19:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User accepted default value 'Day 9 (Day 9)'	Michelle Saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:19:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:19:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:19:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User accepted default value 'Day 14 (Day 14)'	Michelle Saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:19:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:19:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:19:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User accepted default value 'Day 21 (Day 21)'	Michelle Saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:19:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:19:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:19:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User accepted default value 'Day 28 (Day 28)'	Michelle Saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:19:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:19:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:15:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	(b) (4) michelle saemann (b) (4)	04 Mar 2021 12:09:50

US3662032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:49

US3662032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:31:49

US3662032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:49

US3662032

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:30
User entered 'SICKD1'	System	25 Feb 2021 18:31:49

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '10:34'	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User entered '24 Feb 2021 10:34'	System	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '173' cm	(b) (4) Angela Snyder (b) (4)	25 Feb 2021 18:32:52
DataPoint set to visible.	(b) (4) System	25 Feb 2021 18:31:49

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '105.23' kg	(b) (4) Angela Snyder (b) (4)	25 Feb 2021 18:32:52
DataPoint set to visible.	(b) (4) System	25 Feb 2021 18:31:49

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '98.0' F	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Oral (Oral)'	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '92'	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User entered 'bpm'	System	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '16'	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User entered 'breaths/min'	System	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '156'	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User entered 'mmHg'	System	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '95'	Angela Snyder (b) (4)	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39
User entered 'mmHg'	System	25 Feb 2021 18:32:52

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39

US3662032

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:39

US3662032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:31:57

US3662032

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:31:57

US3662032

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:19:44

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:33:02

US3662032

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:19:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:14:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:33:02

US3662032

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

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Jan 2021 16:15:43

US3662032

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

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	(b) (4) Angela Snyder (b) (4)	11 Jan 2021 16:15:43
	(b) (4)	

US3662032

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

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[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 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	11 Jan 2021 16:15:43

US3662032

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

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 16:15:43

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:57:09

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[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 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered '0'	(b) (4) Angela Snyder (b) (4)	09 Apr 2021 12:46:34
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 07:44:51

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:57:09

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 06:46:35
Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 12:46:49
User entered 'Amendment 6 or later (Amendment 6 or later)'	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 12:46:34
User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:01:08
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:44:51

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:57:09

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:57:09

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:51:29
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 12:57:09

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:51:29
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	11 Jan 2021 12:57:09

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:57:09

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '1'	System	11 Jan 2021 12:57:09

US3662032

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

Form: Unblinding

Generated On: 10 Jun 2021 09:19:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'I'	System	11 Jan 2021 12:57:09

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '173' cm	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '105.2' kg	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '35.14985'	System	11 Jan 2021 16:30:43
DataPoint set to visible.	System	11 Jan 2021 12:57:09

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '173' cm	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '105.2' kg	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '35.14985'	System	11 Jan 2021 16:30:43
DataPoint set to visible.	System	11 Jan 2021 12:57:09

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User accepted default value 'Pre-Dose (PREDOSE)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	(b) (4) Angela Snyder (b) (4)	11 Jan 2021 16:30:43
	(b) (4)	

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '07:15'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '11 Jan 2021 07:15'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.3' F	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'infrared thermometer'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '68'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'bpm'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '16'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'breaths/min'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '129'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'mmHg'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '88'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'mmHg'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '173' cm	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '105.2' kg	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:19:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '35.14985'	System	11 Jan 2021 16:30:43
DataPoint set to visible.	System	11 Jan 2021 12:57:09

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User accepted default value 'Post-Dose (POSTDOSE)'	Angela Snyder (b) (4) (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	(b) (4) Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:22'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '11 Jan 2021 08:22'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.4' F	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'infrared thermometer'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '72'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'bpm'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '16'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'breaths/min'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '130'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'mmHg'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '90'	Angela Snyder (b) (4)	11 Jan 2021 16:30:43

US3662032

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'mmHg'	System	11 Jan 2021 16:30:43

US3662032

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Jan 2021 16:30:56

US3662032

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	Angela Snyder (b) (4)	11 Jan 2021 16:30:56

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:58:30

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:58:30

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

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 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:58:30

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'mRNA-1273'	System	11 Jan 2021 12:58:30
DataPoint set to visible.	System	11 Jan 2021 12:57:09

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:58:30

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '07:52'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:58:30

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '11 Jan 2021 07:52'	System	11 Jan 2021 12:58:30

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 12:58:30

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'ONCE'	System	11 Jan 2021 12:58:30

US3662032

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

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 12:58:30

US3662032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Jan 2021 16:31:21

US3662032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	(b) (4) Angela Snyder (b) (4)	11 Jan 2021 16:31:21
	(b) (4)	

US3662032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '07:40'	Angela Snyder (b) (4)	11 Jan 2021 16:31:21

US3662032

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '11 Jan 2021 07:40'	System	11 Jan 2021 16:31:21

US3662032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Jan 2021 16:31:39

US3662032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '11 Jan 2021'	Angela Snyder (b) (4)	11 Jan 2021 16:31:39

US3662032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '07:35'	Angela Snyder (b) (4)	11 Jan 2021 16:31:39

US3662032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:19:44

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered '11 Jan 2021 07:35'	System	11 Jan 2021 16:31:39

US3662032

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

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	11 Jan 2021 16:31:44

US3662032

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

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:19
User entered 'I'	System	11 Jan 2021 16:31:44

US3662032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	21 Jan 2021 17:08:56

US3662032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '19 Jan 2021'	Angela Snyder (b) (4)	21 Jan 2021 17:08:56

US3662032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	21 Jan 2021 17:08:56

US3662032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	Angela Snyder (b) (4)	21 Jan 2021 17:08:56

US3662032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	21 Jan 2021 17:09:01

US3662032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User entered 'I'	System	21 Jan 2021 17:09:01

US3662032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:04:38
User entered '1'	System	21 Jan 2021 17:09:01
DataPoint set to visible.	System	21 Jan 2021 17:09:01

US3662032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Feb 2021 14:12:32

US3662032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '18 Feb 2021'	Angela Snyder (b) (4)	18 Feb 2021 14:12:32

US3662032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	18 Feb 2021 14:12:32

US3662032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'OLD29'	System	18 Feb 2021 14:12:32

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User accepted default value 'Pre-Dose (PREDOSE)'	Angela Snyder (b) (4) (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '18 Feb 2021'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '07:13'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered '18 Feb 2021 07:13'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.4' F	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'infrared thermometer'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '72'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'bpm'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '16'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'breaths/min'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '148'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mmHg'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '88'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mmHg'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User accepted default value 'Post-Dose (POSTDOSE)'	Angela Snyder (b) (4) (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '18 Feb 2021'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:42'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered '18 Feb 2021 08:42'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '97.4' F	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Other (Other)'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'infrared thermometer'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '78'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'bpm'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '16'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'breaths/min'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '146'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mmHg'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '90'	Angela Snyder (b) (4)	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mmHg'	System	18 Feb 2021 14:14:00

US3662032

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Feb 2021 14:14:09

US3662032

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '18 Feb 2021'	Angela Snyder (b) (4)	18 Feb 2021 14:14:09

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'mRNA-1273'	System	18 Feb 2021 13:16:22
DataPoint set to visible.	System	21 Jan 2021 17:09:01

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '08:12'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered '18 Feb 2021 08:12'	System	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'ONCE'	System	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:19:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'INTRAMUSCULAR'	System	18 Feb 2021 13:16:22

US3662032

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Angela Snyder (b) (4)	18 Feb 2021 14:14:14

US3662032

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:30:49
User entered 'I'	System	18 Feb 2021 14:14:14

US3662032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Feb 2021 15:23:54

US3662032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '25 Feb 2021'	Angela Snyder (b) (4)	26 Feb 2021 15:23:54

US3662032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	26 Feb 2021 15:23:54

US3662032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:19:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	26 Feb 2021 15:23:54

US3662032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Feb 2021 15:23:59

US3662032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:19:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:46:06
User entered 'I'	System	26 Feb 2021 15:23:59

US3662032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:25:48

US3662032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '18 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:25:48

US3662032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[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 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4)	25 Mar 2021 18:25:48

US3662032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:19:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User entered 'OLD57'	System	25 Mar 2021 18:25:48

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '18 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '07:09'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User entered '18 Mar 2021 07:09'	System	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '97.7' F	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (Other)'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'infrared thermometer'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '83'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User entered 'bpm'	System	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '16'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User entered 'breaths/min'	System	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '140'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User entered 'mmHg'	System	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '92'	Angela Snyder (b) (4)	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User entered 'mmHg'	System	25 Mar 2021 18:26:59

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49

US3662032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:19:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49

US3662032

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:27:11

US3662032

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:19:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '18 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:27:11

US3662032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:27:41

US3662032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '18 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:27:41

US3662032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '07:16'	Angela Snyder (b) (4)	25 Mar 2021 18:27:41

US3662032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:19:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:09:49
User entered '18 Mar 2021 07:16'	System	25 Mar 2021 18:27:41

US3662032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:19:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:34:40

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear canal erythema, LLT: Erythema ear canal - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	29 Mar 2021 07:12:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 07:12:21
User closed query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:58:08
Data point term sent to Coder	System	26 Mar 2021 14:07:09
Coding entries removed.	michelle saemann (b) (4)	26 Mar 2021 14:07:05
Signature has been broken.	(b) (4) michelle saemann (b) (4)	26 Mar 2021 14:07:05
User entered 'ERYTHEMA PRESENT IN BILATERAL EXTERNAL EAR CANALS. NO EXUDATE, non urticarial' reason for change: Per Query Resolution	(b) (4) michelle saemann (b) (4)	26 Mar 2021 14:07:05
Query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. (Site from DM).	michelle saemann (b) (4)	26 Mar 2021 14:05:41
'answered with 'no urticaria documented in source' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:10:29
User opened query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear canal erythema, LLT: Erythema ear canal - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Mar 2021 08:48:10

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:48:10
Data point term sent to Coder	System	25 Feb 2021 18:36:47
User entered 'erythema present in bilateral external ear canals. no exudate'	Angela Snyder (b) (4) (b) (4)	25 Feb 2021 18:35:54

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:35:54

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 18:35:54

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	25 Feb 2021 18:35:54

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:31:21
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 14:20:52
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 14:20:35
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 14:20:35
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:36:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 21:18:02
User entered 'None (NONE)'	Angela Snyder (b) (4) (b) (4)	25 Feb 2021 18:35:54

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Signature has been broken.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:06:38
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'l'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Feb 2021 18:35:54

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 18:36:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 18:36:04
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Angela Snyder (b) (4)	25 Feb 2021 18:36:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 18:35:54
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

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 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:35:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 18:35:54

US3662032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 18:35:54

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nose bleed - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 23:46:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Feb 2021 23:46:04
Data point term sent to Coder	System	25 Feb 2021 18:37:50
User entered 'nose bleed in right nostril'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '19 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 18:52:06
User entered '22:00' reason for change: Data Entry Error	Angela Snyder (b) (4)	25 Feb 2021 18:52:06
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 18:36:53
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Feb 2021 22:00'	System	25 Feb 2021 18:52:06
User entered empty.	System	25 Feb 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Feb 2021 15:24:42
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4)	25 Feb 2021 18:37:21
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	26 Feb 2021 15:24:57
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Feb 2021 15:24:57
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Feb 2021 15:24:42
User entered '24 Feb 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Feb 2021 15:24:42
User entered empty; reason for change Data Entry Error	Angela Snyder (b) (4)	25 Feb 2021 18:37:21
User entered '24 Feb 2021'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 15:25:18
User entered '18:00' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Feb 2021 15:25:18
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Feb 2021 15:24:42
User closed query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 18:37:21
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Feb 2021 18:36:53
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Feb 2021 18:00'	System	26 Feb 2021 15:25:18
User entered empty.	System	25 Feb 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Feb 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Feb 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'None (NONE)'	(b) (4) Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Feb 2021 15:24:57
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Angela Snyder (b) (4)	25 Feb 2021 18:37:21
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

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 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Feb 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:20:03
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'Subject was assessed ' (Site from DM).	Angela Snyder (b) (4)	30 Mar 2021 10:35:09
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:30:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Community acquired pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 21:19:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 21:19:58
Data point term sent to Coder	System	08 Mar 2021 19:31:19
User entered 'community acquired pneumonia of right lower lobe of lung'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '26 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:30:26

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:20:01
Query 'Per MM, please provide the end date.' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	30 Mar 2021 11:12:33
	(b) (4)	
Signature has been broken.	Angela Snyder (b) (4)	30 Mar 2021 11:12:07
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	30 Mar 2021 11:12:07
	(b) (4)	
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:30:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
Signature has been broken.	Angela Snyder (b) (4)	30 Mar 2021 11:12:07
	(b) (4)	
User entered '5 Mar 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	30 Mar 2021 11:12:07
	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:30:26

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Mar 2021 19:30:26

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	08 Mar 2021 19:30:26

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '1'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Signature has been broken.	(b) (4)	
	Angela Snyder (b) (4)	30 Mar 2021 11:12:07
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Angela Snyder (b) (4)	30 Mar 2021 11:12:07
Data Entry Error	(b) (4)	
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

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 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:30:26
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 19:30:26

US3662032

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 19:30:26

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rhinoviral infections, PT: Rhinovirus infection, LLT: Rhinovirus infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Mar 2021 21:24:56
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 21:24:56
Data point term sent to Coder	System	08 Mar 2021 19:32:20
User entered 'enterovirus human rhinovirus infection, unspecified'	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 19:31:54

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '24 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:31:54

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '27 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:31:54

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	08 Mar 2021 19:31:54

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[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 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:31:54
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 19:31:54

US3662032

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 19:31:54

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Mar 2021 10:07:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:07:20
Data point term sent to Coder	System	25 Mar 2021 18:37:09
User entered 'worsening osteoarthritis of left hip (increase from grade 2)'	Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '3 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '5 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '1'	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:36:53
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 18:36:53

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative hip pain - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 03:55:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 03:55:27
Data point term sent to Coder	System	25 Mar 2021 18:39:12
User entered 'left hip pain, s/p hip replacement'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '5 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:38:48

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:38:48

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:38:48

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '1'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:38:48

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:38:48
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 18:38:48

US3662032

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 18:38:48

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Nose bleeds - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 18:41:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 18:41:29
Data point term sent to Coder	System	25 Mar 2021 18:40:15
User entered 'nose bleeds'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '5 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:39:38

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '18 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:39:38

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:39:38

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:39:38

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:39:38
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 18:39:38

US3662032

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 18:39:38

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Incision site discharge, LLT: Incision site serosanguineous discharge - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 09:56:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 09:56:42
Data point term sent to Coder	System	25 Mar 2021 18:41:15
User entered 'bright red sanguineous drainage from left hip incision'	Angela Snyder (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Yes (Y)'	Angela Snyder (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '18 Mar 2021'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Yes (Y)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	25 Mar 2021 18:40:29
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4) (b) (4)	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Mar 2021 18:40:29

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as SOC: Congenital, familial and genetic disorders, HLG: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type IIa hyperlipidaemia, LLT: Pure hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 16:39:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 16:39:14
Data point term sent to Coder	System	29 Mar 2021 16:37:48
User entered 'pure hypercholesterolemia'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '22 Dec 2020'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 16:37:08

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 16:37:08

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	(b) (4) Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Mar 2021 16:37:08

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Related (NOT RELATED)'	(b) (4) Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Angela Snyder (b) (4)	29 Mar 2021 16:37:08

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'I'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Mar 2021 16:37:08

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:37:08
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Mar 2021 16:37:08

US3662032

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 16:37:08

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 15:11:02
User entered 'USA-US088-2021-mRNA-1273-P301000012'	System	14 Apr 2021 15:10:59
User entered 'New'	(b) (4), (b) (6)	14 Apr 2021 15:10:59

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Medical device site joint infection, LLT: Medical device site joint infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:13:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:13:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:02:44
Data point term sent to Coder	System	13 Apr 2021 18:59:59
User entered 'Infection/inflammation reaction due to internal left hip prosthesis'	michelle saemann (b) (4) (b) (4)	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'Yes (Y)'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'No (N)'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'No (N)'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '08 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	14 Apr 2021 13:45:19
	(b) (4)	
User entered '07 Apr 2021'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered empty.	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:05:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered 'Yes (Y)'	(b) (4) michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered empty.	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered empty.	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) michelle saemann (b) (4)	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'Yes (Y)'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '0'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '0'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:54:19
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent discharge summary on 4/21 @ 14:22' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 18:22:22
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:05:49
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		20 Apr 2021 19:43:08
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		20 Apr 2021 19:43:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Apr 2021 19:42:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 16:31:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

2451 of 3584

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'd/c date unknown at this time' (Site from System).	michelle saemann (b) (4)	13 Apr 2021 19:00:00
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Apr 2021 18:59:27
User entered '1'	michelle saemann (b) (4)	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '08 Apr 2021'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Signature has been broken.	michelle saemann (b) (4)	20 Apr 2021 19:43:08
User entered '13 Apr 2021' reason for change: Data Entry Error	michelle saemann (b) (4)	20 Apr 2021 19:43:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered empty.	michelle saemann (b) (4)	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Please keep query open until response can be updated to Yes or No. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 16:16:12
Query 'Per CDM Re-Query: Please keep query open until response can be updated to Yes or No. Thank you' answered with 'updated' (Site from DM).	michelle saemann (b) (4)	20 Apr 2021 19:42:43
Signature has been broken.	michelle saemann (b) (4)	20 Apr 2021 19:42:17
User entered 'No (N)' reason for change: New Information	michelle saemann (b) (4)	20 Apr 2021 19:42:17
User opened query 'Per CDM Re-Query: Please keep query open until response can be updated to Yes or No. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 17:34:49
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 17:34:10
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'It will be. we are waiting on records.' (Site from System).	michelle saemann (b) (4)	13 Apr 2021 19:00:02
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	13 Apr 2021 18:59:27
User entered 'Unknown (UNK)'	michelle saemann (b) (4)	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered empty.	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '0'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '0'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '0'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) michelle saemann (b) (4)	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '0'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '1'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '1'	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:05:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) michelle saemann (b) (4)	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered empty.	michelle saemann (b) (4)	13 Apr 2021 18:59:27
	(b) (4)	

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide white blood cell count, blood culture results, wound culture results, and any other pertinent information for the subject's infection.' answered with 'requested results were not unavailable with the records sent to us, all we had was what was sent in the discharge summary that I sent which included the MRSA and pseudomonas.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:19:55
User opened query 'PV Query: Please provide white blood cell count, blood culture results, wound culture results, and any other pertinent information for the subject's infection.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:06:30
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 20:15:08
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:54:43
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:54:35
User closed query 'PV Query: Please provide any signs and symptoms experienced by the subject before the event.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:54:31
User closed query 'PV Query: The event verbatim contains 2 events. Kindly consider spitting the event verbatim in order to accurately code the events.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:54:29
User closed query 'PV Query: Please provide the details of the procedure - internal left hip prosthesis insertion' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:54:24
Query 'PV Query: Please provide any signs and symptoms experienced by the subject before the event.' answered with 'See narrative' (Site from Safety).	michelle saemann (b) (4)	21 Apr 2021 17:56:45
Query 'PV Query: Please provide the details of the procedure - internal left hip prosthesis insertion' answered with 'See narrative' (Site from Safety).	michelle saemann (b) (4)	21 Apr 2021 17:56:39

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
Signature has been broken.	michelle saemann (b) (4)	21 Apr 2021 17:56:27
User entered 'PARTICIPANT ADMITTED FOR REVISED HIP JOINT REPLACEMENT. WE ARE WORKING ON OBTAINING RECORDS. WILL UPDATE ONCE MORE INFORMATION IS OBTAINED.	michelle saemann (b) (4)	21 Apr 2021 17:56:27
4/21/21 Participant had left hip arthroplasty on 3/5/21. Developed bloody drainage from the incision around post op week 3. On 4/7/21 post op f/u visit he reported continued drainage. Small part of incision was opened with hemostats and could be probed 2-2.5cm. After exam, it was decided that participant would be scheduled for a post left total hip arthroplasty revision with incision and debridement and polyethylene exchange. Procedure done on 4/8/21. Cultures revealed MRSA and pseudomonas. At discharge, pt. sent home on IV ABT.' reason for change: Data Entry Error		
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'Left hip arthroplasty was done on 3/5/21. No other risk factors noted. ' (Site from Safety).	michelle saemann (b) (4)	21 Apr 2021 17:50:26
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'COVID test not noted in records that we received. ' (Site from Safety).	michelle saemann (b) (4)	21 Apr 2021 17:48:38
Query 'PV Query: The event verbatim contains 2 events. Kindly consider spitting the event verbatim in order to accurately code the events. ' answered with 'Per records this is listed as one event. ' (Site from Safety).	michelle saemann (b) (4)	21 Apr 2021 16:03:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Please tell me what lab and diagnostic tests you would like. ' (Site from Safety).	michelle saemann (b) (4)	21 Apr 2021 16:02:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

2469 of 3584

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:05:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:05:13
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:04:53
User opened query 'PV Query: Please provide any signs and symptoms experienced by the subject before the event. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:04:46
User opened query 'PV Query: The event verbatim contains 2 events. Kindly consider spitting the event verbatim in order to accurately code the events. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:04:38
User opened query 'PV Query: Please provide the details of the procedure - internal left hip prosthesis insertion' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:04:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered 'Participant admitted for revised hip joint replacement. We are working on obtaining records. Will update once more information is obtained.'	(b) (4) michelle saemann (b) (4)	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 18:59:27

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Hematoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 15:30:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 15:30:59
Data point term sent to Coder	System	25 Apr 2021 14:54:13
Query 'DM-Coding: It is a medical and surgical procedure and not appropriate as an adverse event. Please enter/add the diagnosis for which this procedure was performed and amend /update the term accordingly.	Coder Import (b) (4) (b) (4)	25 Apr 2021 14:53:48
' canceled (Site from System).		
User opened query 'DM-Coding: It is a medical and surgical procedure and not appropriate as an adverse event. Please enter/add the diagnosis for which this procedure was performed and amend /update the term accordingly.	Coder Import (b) (4) (b) (4)	23 Apr 2021 15:53:45
' (Site from System).		
Data point term sent to Coder	System	20 Apr 2021 12:05:42
User entered 'Draining hematoma, status post left total hip arthroplasty'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User entered '8 Apr 2021'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Apr 2021'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[None](#)

Audit	User	Time (GMT)
User entered '0'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 12:05:37

US3662032

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:19:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 12:05:37

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:19:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:56:22

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Sep 2020 23:59:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 23:59:42
Data point term sent to Coder	System	23 Sep 2020 15:57:56
User entered 'IBUPROFEN'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:57:14

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:55:59
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate. ' answered with 'Added events to med history and updated all logs to match med indication.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:43:10
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:41:18
User entered 'ANKLE/KNEES SORENESS'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:57:14

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered '200'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:57:14

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'as needed (PRN)'	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '01 Jul 2018'	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:57:14
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 15:57:14

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 15:57:14

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 15:57:14

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Sep 2020 15:58:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:58:39
Data point term sent to Coder	System	23 Sep 2020 15:57:55
User entered 'MULTIVITAMINS'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:57:50

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	28 Oct 2020 22:59:57
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'SUPPLEMENT'	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:57:50

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '1'	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'capsule (CAPSULE)'	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:57:50

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '01 Jul 2018'	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:57:50
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:57:50

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:57:50

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 15:57:50

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:26:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:26:01
Data point term sent to Coder	System	24 Feb 2021 17:25:23
Coding entries removed.	(b) (4), (b) (6)	24 Feb 2021 17:24:32
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	22 Feb 2021 14:56:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:59:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:59:40
Data point term sent to Coder	System	23 Sep 2020 15:58:57
User entered 'CLONIDINE'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:58:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 17:24:32
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:24:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'HIGH BLOOD PRESSURE'	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '.2'	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'mg (mg)'	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:58:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'twice daily (BID)'	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered empty.	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '01 Jul 2006'	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Yes (Y)'	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:58:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 15:58:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 15:58:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:58:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 15:58:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:26:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:26:01
Data point term sent to Coder	System	24 Feb 2021 17:25:23
Coding entries removed.	(b) (4), (b) (6)	24 Feb 2021 17:24:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	22 Feb 2021 14:56:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:00:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:00:35
Data point term sent to Coder	System	23 Sep 2020 15:59:58
User entered 'HYDROCHLOROTHIAZIDE'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 15:59:33

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 17:24:48
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:24:48
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'HIGH BLOOD PRESSURE'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '50'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'once daily (QD)'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '01 Jul 2006'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 15:59:33
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:59:33

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 15:59:33

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 15:59:33

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:26:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:26:02
Data point term sent to Coder	System	24 Feb 2021 17:25:23
Coding entries removed.	(b) (4), (b) (6)	24 Feb 2021 17:25:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	22 Feb 2021 14:56:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:01:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:01:41
Data point term sent to Coder	System	23 Sep 2020 16:01:01
User entered 'LOSARTAN'	Brenda Miller (b) (4) (b) (4)	23 Sep 2020 16:00:12

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	24 Feb 2021 17:25:07
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:25:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'HIGH BLOOD PRESSURE'	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '100'	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'mg (mg)'	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'once daily (QD)'	(b) (4) Brenda Miller (b) (4) (b) (4)	23 Sep 2020 16:00:12

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'Oral (ORAL)'	(b) (4) Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '01 Jul 2006'	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered '0'	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'Yes (Y)'	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered empty.	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
	(b) (4)	
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 16:00:12
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:00:12

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:00:12

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:00:12

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
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)	08 Apr 2021 17:01:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 17:01:49
Data point term sent to Coder	System	08 Apr 2021 17:01:18
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 17:00:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 21:18:02
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)	08 Mar 2021 19:26:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:26:42
Data point term sent to Coder	System	08 Mar 2021 19:26:14
User entered 'Tylenol'	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User closed query 'Per CDM, DM CLR RQ: Per page 47 of CCGs v5.0, if illness sample is negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please review if an alternative diagnosis should be recorded on the AE page and the Con Med and AE pages reconciled, else clarify. Thank you. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Carl Fichtenbaum (b) (4)	09 Apr 2021 09:18:30 08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per page 47 of CCGs v5.0, if illness sample is negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please review if an alternative diagnosis should be recorded on the AE page and the Con Med and AE pages reconciled, else clarify. Thank you. ' answered with 'updated' (Site from DM). Signature has been broken.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Apr 2021 17:01:22 08 Apr 2021 17:00:52
User entered ' (J18.9) community acquired pneumonia of right lower lobe of lung' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:00:52
User opened query 'Per CDM, DM CLR RQ: Per page 47 of CCGs v5.0, if illness sample is negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please review if an alternative diagnosis should be recorded on the AE page and the Con Med and AE pages reconciled, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:39:35

PRODUCTION RELEASE (v12.003
EAB) (1725)

2601 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:39:35
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'AE is on symptom log, the med was taken for this and will not be on AE log' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:18:31
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:20:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'headache, AE part of symptom log'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '1000'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'mg (mg)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '19 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '27 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User entered '2'	System	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User entered '1'	System	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:32
User entered '804 (804)'	System	08 Mar 2021 19:26:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:06:36
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 Apr 2021 05:06:36
Data point term sent to Coder	System	08 Apr 2021 17:02:20
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 17:01:51
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 21:18:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 09:29:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 09:29:54
Data point term sent to Coder	System	08 Mar 2021 19:27:15
User entered 'ibuprofen'	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User closed query 'Per CDM, DM CLR RQ: Per page 47 of CCGs v5.0, if illness sample is negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please review if an alternative diagnosis should be recorded on the AE page and the Con Med and AE pages reconciled, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:20:55
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per page 47 of CCGs v5.0, if illness sample is negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please review if an alternative diagnosis should be recorded on the AE page and the Con Med and AE pages reconciled, else clarify. Thank you. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:01:57
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 17:01:51
User entered ' (J18.9) community acquired pneumonia of right lower lobe of lung' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:01:51
User opened query 'Per CDM, DM CLR RQ: Per page 47 of CCGs v5.0, if illness sample is negative, an alternative diagnosis should be determined and recorded as an adverse event. (i.e. Covid like-illness, possible respiratory tract infection viral (if respiratory symptoms), possible viral syndrome). Please review if an alternative diagnosis should be recorded on the AE page and the Con Med and AE pages reconciled, else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:40:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

2620 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:40:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'AE is on symptom log, the med was taken for this and will not be on AE log' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:19:07
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:20:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'headache, AE part of symptom log'	(b) (4) Angela Snyder (b) (4) (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '800'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'mg (mg)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '19 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '27 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User entered '2'	System	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User entered '1'	System	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:33
User entered '804 (804)'	System	08 Mar 2021 19:26:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Mar 2021 07:00:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:00:42
Data point term sent to Coder	System	08 Mar 2021 19:28:17
User entered 'zithromax'	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 19:28:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'community acquired pneumonia of right lower lobe of lung'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '250'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '26 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:28:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 19:28:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 19:28:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Mar 2021 19:28:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFPODOXIME PROXETIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Mar 2021 23:57:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:57:50
Data point term sent to Coder	System	08 Mar 2021 19:30:18
User entered 'cefpodoxime proxetil'	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'community acquired pneumonia of right lower lobe of lung'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '200'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'mg (mg)'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '26 Feb 2021'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered '0'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Signature has been broken.	Angela Snyder (b) (4)	26 Mar 2021 11:23:07
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Mar 2021 11:23:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'Yes (Y)'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Signature has been broken.	Angela Snyder (b) (4)	26 Mar 2021 11:23:07
User entered '5 Mar 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Mar 2021 11:23:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered empty.	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 21:18:02
User entered 'No (N)'	Angela Snyder (b) (4)	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User entered '2'	System	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User entered '1'	System	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:40
User entered '804 (804)'	System	08 Mar 2021 19:29:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 14:58:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:58:51
Data point term sent to Coder Coding entries removed.	System Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:56:09 08 Apr 2021 12:55:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:11:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:11:49
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 16:58:25 07 Apr 2021 16:57:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 08:40:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 08:40:46
Data point term sent to Coder	System	26 Mar 2021 11:25:35
User entered 'zofran'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:21:10
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:55:46
User entered 'UNK' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:55:11
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:47:59
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:47:59
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:35:59
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:35:07
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:56:42
User entered 'dose unknown'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:55:11
User entered 'UNK/UNKOWN' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:35:41
User entered 'Unit unknown'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:57:27
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:55:30
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:57:27
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User entered empty.	System	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User entered empty.	System	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:51
User entered empty.	System	26 Mar 2021 11:25:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 17:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:05:42
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 17:04:50 07 Apr 2021 17:04:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 11:28:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Mar 2021 11:28:44
Data point term sent to Coder User entered 'tylenol'	System Angela Snyder (b) (4)	26 Mar 2021 11:27:37 26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left hip pain, s/p left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 07:17:34
Query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated, dose/unit/route unknown' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:04:23
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:04:05
User opened query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:56:31
User entered '10'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'unknown' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:04:05
User entered 'mg/ml'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:04:05
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'unknown' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:04:05
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User entered empty.	System	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User entered empty.	System	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:56
User entered empty.	System	26 Mar 2021 11:26:39

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 09:46:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:46:07
Data point term sent to Coder	System	26 Mar 2021 11:29:38
User entered 'tranexamic acid'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '10'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mL (mL)'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'route is infiltrate'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User entered empty.	System	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User entered empty.	System	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:15:57
User entered empty.	System	26 Mar 2021 11:28:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: TOBRAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 14:59:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 14:59:41
Data point term sent to Coder	System	08 Apr 2021 12:58:14
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 12:58:13
Coding entries removed.	(b) (4), (b) (6)	08 Apr 2021 12:58:13
User entered 'TOBRAMYCIN 1.2G' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 12:58:13
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: TOBRAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 10:27:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 10:27:40
Data point term sent to Coder	System	07 Apr 2021 16:24:15
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 16:24:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: TOBRAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:11:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 13:11:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

2728 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	26 Mar 2021 11:30:39
User entered 'tobramycin'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User closed query 'Per CDM, DM CLR RQ: Please review if the strength should be included in the Name of the Medication and not in the Indication field. Kindly update as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	09 Apr 2021 09:21:55
Query 'Per CDM, DM CLR RQ: Please review if the strength should be included in the Name of the Medication and not in the Indication field. Kindly update as appropriate. ' answered with 'updated' (Site from DM).	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'LEFT TOTAL HIP ARTHROPLASTY' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 12:58:13
User opened query 'Per CDM, DM CLR RQ: Please review if the strength should be included in the Name of the Medication and not in the Indication field. Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:16:25
User entered 'LEFT TOTAL HIP ARTHROPLASTY 1.2g' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:24:07
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 07:16:27
' (Site from DM).		
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.	(b) (4), (b) (6)	07 Apr 2021 16:24:14
' answered with 'updated' (Site from DM).		
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:24:07
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.	(b) (4), (b) (6)	07 Apr 2021 06:56:07
' (Site from DM).		
User entered '1.2'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:24:07
User entered 'g (g)'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Application' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:24:07
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Topical (TOPICAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User entered empty.	System	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User entered empty.	System	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:03
User entered empty.	System	26 Mar 2021 11:30:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 11:53:43
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 Mar 2021 11:53:43
Data point term sent to Coder	System	26 Mar 2021 11:31:42
User entered 'rivaroxaban'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:31:59
Query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 16:05:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 16:05:41
User opened query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:26:09
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'post surgical prophylaxis left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '10'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once daily (QD)'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '18 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User entered 'I'	System	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User entered 'I'	System	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:05
User entered '804 (804)'	System	26 Mar 2021 11:31:20

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 15:10:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:10:06
Data point term sent to Coder	System	08 Apr 2021 12:58:10
Coding entries removed.	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 12:57:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:29:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:29:48
Data point term sent to Coder	System	07 Apr 2021 17:03:46
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 17:03:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:57:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:57:42
Data point term sent to Coder	System	26 Mar 2021 11:32:42
User entered 'morphine'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:22:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	08 Apr 2021 12:58:11
User entered 'UNK' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Apr 2021 12:57:52
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:50:07
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:50:07
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	07 Apr 2021 13:41:36
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:41:10
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:55:55
User entered 'dose unknown'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:57:52
User entered 'UNK/UNKOWN' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:41:10
User entered 'unit unknown'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:03:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:57:52
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:03:26
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User entered empty.	System	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User entered empty.	System	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:07
User entered empty.	System	26 Mar 2021 11:32:26

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 08:25:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:25:35
Data point term sent to Coder	System	07 Apr 2021 17:03:46
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 17:03:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: MIDAZOLAM HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:06:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:06:35
Data point term sent to Coder	System	26 Mar 2021 11:34:43
User entered 'midazolam hcl'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:23:01
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 12:58:49
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 12:58:40
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:49:45
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:49:45
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:43:29
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:43:11
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:55:43
User entered 'dose unknown'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:33:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

2786 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK/UNKOWN' reason for change:	(b) (4)	
Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:43:11
User entered 'unit unknown'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:33:54
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:03:00
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'unknown' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:03:00
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User entered empty.	System	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User entered empty.	System	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:13
User entered empty.	System	26 Mar 2021 11:33:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 10:27:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:27:37
Data point term sent to Coder	System	26 Mar 2021 11:35:44
User entered 'methocarbamol'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '500'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'as needed (PRN)'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:34:15
User entered 'Yes (Y)'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:35:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:34:15
User entered empty.	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:35:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User entered empty.	System	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User entered empty.	System	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:14
User entered empty.	System	26 Mar 2021 11:35:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 12:39:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 12:39:46
Data point term sent to Coder	System	26 Mar 2021 11:37:45
User entered 'meloxicam; mobic'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left hip pain, s/p left hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '15'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once daily (QD)'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '18 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User entered 'I'	System	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User entered '1'	System	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:19
User entered '804 (804)'	System	26 Mar 2021 11:36:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 11:40:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:40:49
Data point term sent to Coder	System	26 Mar 2021 11:39:45
User entered 'lactated ringers'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 07:50:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:59:45
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 12:59:37
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:49:25
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:49:25
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	07 Apr 2021 13:45:21
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:44:55
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:55:15
User entered 'dose unknown'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK/UNKNOWN' reason for change:	(b) (4)	
Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:44:55
User entered 'unit unknown'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:39:00
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User entered empty.	System	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User entered empty.	System	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:26
User entered empty.	System	26 Mar 2021 11:39:00

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL HYDROCHLORIDE, PRODUCTSYNONYM: LABETALOL HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 17:04:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:04:46
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 17:03:36 07 Apr 2021 17:02:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL HYDROCHLORIDE, PRODUCTSYNONYM: LABETALOL HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:41:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:41:42
Data point term sent to Coder User entered 'labetalol hcl'	System Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:40:49 26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:23:41
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:00:20
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:00:03
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:48:47
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:48:47
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	07 Apr 2021 13:46:53
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:46:21
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:55:05
User entered 'dose unknown'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

PRODUCTION RELEASE (v12.003
EAB) (1725)

2858 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK/UNKNOWN' reason for change:	(b) (4)	
Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:46:21
User entered 'unit unknown'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:40:17
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:02:41
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'unknown' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:02:41
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User entered empty.	System	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User entered empty.	System	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:27
User entered empty.	System	26 Mar 2021 11:40:17

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:22:38
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 Apr 2021 05:22:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:47:48
Data point term sent to Coder	System	08 Apr 2021 13:04:26
Coding entries removed.	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 13:03:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:57:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:57:45
Data point term sent to Coder	System	07 Apr 2021 17:03:47
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 17:03:43

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:18:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 14:18:32
Data point term sent to Coder	System	26 Mar 2021 11:42:49
User entered 'ketorolac tromethamine'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:23:49
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:03:15
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 13:02:56
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:48:17
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:48:17
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	07 Apr 2021 13:48:17
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:47:59
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:54:56
User entered 'dose unknown'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

2877 of 3584

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Apr 2021 13:03:48
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	07 Apr 2021 13:47:59
User entered 'unit unknown'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:42:27
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:03:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 13:03:48
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:03:43
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User entered empty.	System	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User entered empty.	System	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:44
User entered empty.	System	26 Mar 2021 11:42:27

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROMORPHONE HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 17:03:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:03:18
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 17:01:30 07 Apr 2021 17:01:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROMORPHONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:44:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:44:44
Data point term sent to Coder User entered 'hydromorphone hcl'	System Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:44:01 26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 07:17:09
Query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated, dose, route and unit were unknown' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:02:22
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 17:01:03
User opened query 'Per DM CLR: Please provide dose in MG instead of ML, as there are various dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:54:28
User entered 'I'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'unknown' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:01:03
User entered 'mg/ml'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:01:03
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'unknown' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 17:01:03
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User entered empty.	System	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User entered empty.	System	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:45
User entered empty.	System	26 Mar 2021 11:43:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDRALAZINE HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 13:02:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 13:02:49
Data point term sent to Coder Coding entries removed.	System Angela Snyder (b) (4) (b) (4)	08 Apr 2021 13:02:24 08 Apr 2021 13:02:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDRALAZINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:00:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 17:00:42
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 16:59:28 07 Apr 2021 16:59:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDRALAZINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:45:47

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	26 Mar 2021 11:45:47
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	26 Mar 2021 11:45:02
User entered 'hydralazine hcl'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:22:19
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	08 Apr 2021 13:02:46
User entered 'UNK' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Apr 2021 13:02:24
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:47:38
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:47:38
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	07 Apr 2021 13:51:23
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:51:06
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:54:17
User entered 'dose unknown'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Apr 2021 13:02:24
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	07 Apr 2021 13:51:06
User entered 'unit unknown'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:44:54
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:59:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Apr 2021 13:02:24
User entered 'unknown' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:59:26
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:44:54
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User entered empty.	System	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User entered empty.	System	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:50
User entered empty.	System	26 Mar 2021 11:44:54

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 14:12:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:12:26
Data point term sent to Coder	System	26 Mar 2021 11:47:03
User entered 'gabapentin'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left hip pain, s/p left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '300'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'three times daily (TID)'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:34:35
User entered 'Yes (Y)'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:46:03
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:34:35
User entered empty.	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:46:03
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User entered '3'	System	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User entered '1'	System	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:52
User entered '804 (804)'	System	26 Mar 2021 11:46:03

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 15:03:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:03:44
Data point term sent to Coder	System	08 Apr 2021 13:01:18
Coding entries removed.	Angela Snyder (b) (4) (b) (4)	08 Apr 2021 13:01:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:24:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:24:45
Data point term sent to Coder	System	07 Apr 2021 16:58:25
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 16:58:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:21
Data point term sent to Coder	System	26 Mar 2021 11:48:03
User entered 'fentanyl'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:24:23
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	08 Apr 2021 13:01:20
User entered 'UNK' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Apr 2021 13:01:03
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:46:51
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:46:51
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	07 Apr 2021 13:52:45
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:52:25
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:54:07
User entered 'dose unknown'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Apr 2021 13:01:03
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	07 Apr 2021 13:52:25
User entered 'unit unknown'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:47:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:58:07
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 13:01:03
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 16:58:07
User entered empty.	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User entered empty.	System	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User entered empty.	System	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:16:56
User entered empty.	System	26 Mar 2021 11:47:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
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)	30 Mar 2021 14:03:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:16
Data point term sent to Coder	System	26 Mar 2021 11:49:04
User entered 'famotidine'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:32:41
Query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 16:07:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 16:06:57
User opened query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:29:35
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'post surgical prophylaxis left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '20'	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:35:01
User entered 'Yes (Y)'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:48:25
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:35:01
User entered empty.	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:48:25
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User entered '2'	System	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User entered '1'	System	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:08
User entered '804 (804)'	System	26 Mar 2021 11:48:25

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	30 Mar 2021 00:50:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:50:24
Data point term sent to Coder	System	26 Mar 2021 11:50:05
User entered 'docusate sodium'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:33:02
Query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 16:08:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 16:07:55
User opened query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:30:31
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'post surgical prophylaxis left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '100'	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:35:19
User entered 'Yes (Y)'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:49:45
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:35:19
User entered empty.	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:49:45
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User entered '2'	System	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User entered '1'	System	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:16
User entered '804 (804)'	System	26 Mar 2021 11:49:45

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:02:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:02:58
Data point term sent to Coder Coding entries removed.	System Angela Snyder (b) (4) (b) (4)	08 Apr 2021 13:00:16 08 Apr 2021 12:59:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:12:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:12:39
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 16:59:28 07 Apr 2021 16:58:41
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:41:16

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'dexamethasone'	Coder Import (b) (4) (b) (4) System Angela Snyder (b) (4) (b) (4)	30 Mar 2021 00:41:16 26 Mar 2021 11:51:05 26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User closed query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 07:47:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' answered with 'data updated' (Site from DM).	Angela Snyder (b) (4)	08 Apr 2021 13:00:00
User entered 'UNK' reason for change: Data Entry Error	Angela Snyder (b) (4)	08 Apr 2021 12:59:43
User opened query 'Per CDM, DM CLR RQ: Per CCGs, if dose is unknown, only "UNK" should be entered into the text field. Kindly update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:46:16
User closed query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:46:16
Query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	07 Apr 2021 13:50:00
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4)	07 Apr 2021 13:49:42
User opened query 'Per DM CLR: Please provide the dose number in numeric format. Consider using dose=1, unit=tab/cap/unknown. Otherwise, if unknown, please enter in dose/unit = UNK/UNKNOWN as per protocol. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:53:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'dose unknown'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4) Angela Snyder (b) (4)	08 Apr 2021 12:59:43
User entered 'UNK/UNKNOWN' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:49:42
User entered 'unit unknown'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:58:41
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	08 Apr 2021 12:59:43
User entered 'unknown' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 16:58:41
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:50:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User entered empty.	System	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User entered empty.	System	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:21
User entered empty.	System	26 Mar 2021 11:50:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Mar 2021 07:08:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:08:06
Data point term sent to Coder	System	26 Mar 2021 11:53:07
User entered 'cefazolin'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '2'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'g (g)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once (ONCE)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User entered empty.	System	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User entered empty.	System	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:26
User entered empty.	System	26 Mar 2021 11:52:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 12:14:43
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 Mar 2021 12:14:43
Data point term sent to Coder	System	26 Mar 2021 11:53:06
User entered 'aspirin'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:33:23
Query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 16:09:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	05 Apr 2021 16:09:08
User opened query 'Per CDM Query: Prophylaxis is entered in the Indication field. Please confirm if Prophylaxis field should be updated to Yes. Thank you ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:32:21
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'post surgical prophylaxis'	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '325'	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once daily (QD)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:35:35
User entered 'Yes (Y)'	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:52:51
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Angela Snyder (b) (4)	29 Mar 2021 16:35:35
User entered empty.	(b) (4)	
	Angela Snyder (b) (4)	26 Mar 2021 11:52:51
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User entered '1'	System	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User entered '1'	System	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:28
User entered '804 (804)'	System	26 Mar 2021 11:52:51

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE BITARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 09:00:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:00:27
Data point term sent to Coder	System	26 Mar 2021 11:55:08
User entered 'acetaminophen; comb; hydrocodone bitartrate'	Angela Snyder (b) (4) (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left hip pain s/p left total hip arthroplasty'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '325/5'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'as needed (PRN)'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '0'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '18 Mar 2021'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'No (N)'	Angela Snyder (b) (4)	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User entered empty.	System	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User entered empty.	System	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:17:40
User entered empty.	System	26 Mar 2021 11:54:48

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
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)	29 Mar 2021 16:33:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 16:33:11
Data point term sent to Coder	System	29 Mar 2021 16:32:40
User entered 'aspirin'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User closed query 'Per DM CLR: Please review response as heart health are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:51:39
Query 'Per DM CLR: Please review response as heart health are considered as prophylaxis. Update as appropriate. ' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:53:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 13:53:36
User opened query 'Per DM CLR: Please review response as heart health are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:53:22
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	29 Mar 2021 16:32:28

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'heart health'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '81'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Mar 2021 16:32:28

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '15 Jul 2018'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Mar 2021 16:32:28
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 16:32:28

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 16:32:28

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 16:32:28

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Mar 2021 16:34:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:34:25
Data point term sent to Coder	System	29 Mar 2021 16:33:44
User entered 'Lipitor'	Angela Snyder (b) (4) (b) (4)	29 Mar 2021 16:33:43

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'hypercholesterolemia'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Mar 2021 16:33:43

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '40'	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'once daily (QD)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Mar 2021 16:33:43

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	29 Mar 2021 16:33:43

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '03 Mar 2021'	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	29 Mar 2021 16:33:43
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 16:33:43

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 16:33:43

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 16:33:43

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN HYDROCHLORIDE, PRODUCTSYNONYM: VANCOMYCIN HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 13:16:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 13:16:54
Data point term sent to Coder	System	20 Apr 2021 12:42:15
Data point term sent to Coder	System	20 Apr 2021 12:12:46
User entered 'vancomycin hcl'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'INFECTION/INFLAMMATION REACTION DUE TO INTERNAL LEFT HIP PROSTH, INIT (MRSA AND PSEUDOMONAS)'	(b) (4)	
reason for change: Data Entry Error	Angela Snyder (b) (4)	20 Apr 2021 12:42:10
User entered 'infection/inflammation reaction due to internal left hip prosth, init (MRSA and pseudomonas'	(b) (4)	
	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '1.5'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'g (g)'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:12:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:12:08
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:12:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:12:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:12:08

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: TOBRAMYCIN SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Apr 2021 07:19:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 07:19:08
Data point term sent to Coder	System	20 Apr 2021 12:42:16
Data point term sent to Coder	System	20 Apr 2021 12:14:47
User entered 'tobramycin sulfate'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:14:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'INFECTION/INFLAMMATION REACTION DUE TO INTERNAL LEFT HIP PROSTH, INIT (MRSA AND PSEUDOMONAS)'	(b) (4)	
reason for change: Data Entry Error	Angela Snyder (b) (4)	20 Apr 2021 12:41:46
User entered 'infection/inflammation reaction due to internal left hip prosth, init (MRSA and pseudomonas'	(b) (4)	
	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '1.2'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'g (g)'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'once (ONCE)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:14:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'UNK'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:14:05
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:14:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:14:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:14:05

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNA ALEXANDRINA EXTRACT, PRODUCTSYNONYM: SENNA CONCENTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Apr 2021 08:31:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:31:27
Data point term sent to Coder	System	20 Apr 2021 12:15:48
User entered 'senna concentrate'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:15:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'constipation prevention post surgical procedure'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:15:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8.6'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'g (g)'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:15:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '13 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:15:02
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:15:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:15:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:15:02

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 13:20:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:20:20
Data point term sent to Coder	System	20 Apr 2021 12:16:52
User entered 'rivaroxaban'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:16:42

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'blood clot prevention post surgical procedure'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '10'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Apr 2021 18:45:13
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '25 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Apr 2021 18:45:13
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:16:42
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:16:42

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:16:42

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:16:42

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANESTHETICS FOR TOPICAL USE, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 13:16:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:16:06
Data point term sent to Coder	System	20 Apr 2021 12:20:02
User entered 'lidocaine patch 5%'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:19:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'left total hip arthroplasty revision with incision and debridement and polyethylene exchange'	(b) (4) Angela Snyder (b) (4)	20 Apr 2021 12:19:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '1'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'patch'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Topical (TOPICAL)'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '13 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:19:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:19:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:19:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:19:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 12:21:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 12:21:56
Data point term sent to Coder	System	20 Apr 2021 12:21:03
User entered 'lactated ringers'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'surgical procedure'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '100'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mL (mL)'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:20:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '10 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:20:19
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:20:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:20:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:20:19

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 12:57:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:57:04
Data point term sent to Coder	System	20 Apr 2021 12:22:03
User entered 'docusate calcium'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:21:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'constipation prevention post surgical procedure'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:21:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '100'	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:21:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Apr 2021 18:45:37
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '26 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Apr 2021 18:45:37
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:21:15
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 12:21:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:21:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:21:15

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 12:48:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:48:55
Data point term sent to Coder	System	20 Apr 2021 12:41:15
Data point term sent to Coder	System	20 Apr 2021 12:23:04
User entered 'ceftriaxone'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:22:53

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'INFECTION/INFLAMMATION REACTION DUE TO INTERNAL LEFT HIP PROSTH, INIT (mrsa and pseudomonas)' reason for change: Data Entry Error	Angela Snyder (b) (4)	20 Apr 2021 12:41:03
User entered 'infection/inflammation reaction due to internal left hip prosth, init'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '2'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'g (g)'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:22:53

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '12 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:22:53
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:22:53

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:22:53

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:22:53

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBACTERIALS FOR SYSTEMIC USE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:08:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:08:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBACTERIALS FOR SYSTEMIC USE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:07:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:07:10
Data point term sent to Coder	System	20 Apr 2021 12:48:19
Data point term sent to Coder	System	20 Apr 2021 12:28:06
User entered 'antibiotic containing calcium phosphate beads; tobramycin;vancomycin;gentamicin'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'left hip wound'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '1.2/1/80'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg/gm/mg'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once (ONCE)'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Left hip wound' reason for change:	Angela Snyder (b) (4)	20 Apr 2021 12:47:31
Data Entry Error	(b) (4)	
User entered 'UNK'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:27:24
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:27:24

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:27:24

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:27:24

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 16:04:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:04:51
Data point term sent to Coder	System	20 Apr 2021 12:30:07
User entered 'vicodin comb; acetaminophen;hydrocodone'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:29:59

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'left total hip arthroplasty revision with incision and debridement and polyethylene exchange'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:29:59

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '325/5'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'as needed (PRN)'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '15 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:29:59
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:29:59

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:29:59

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:29:59

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 12:57:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:57:05
Data point term sent to Coder	System	20 Apr 2021 12:31:08
User entered 'gabapentin'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:30:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'left total hip arthroplasty revision with incision and debridement and polyethylene exchange'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:30:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '300'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'three times daily (TID)'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:30:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '13 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:30:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Apr 2021 12:30:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:30:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:30:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
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)	20 Apr 2021 12:55:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:55:53
Data point term sent to Coder	System	20 Apr 2021 12:33:09
User entered 'famotidine'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:32:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'post surgical nausea'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '20'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '13 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:32:49
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 12:32:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:32:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:32:49

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE GLUCONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 12:50:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 12:50:10
Data point term sent to Coder	System	20 Apr 2021 12:34:10
User entered 'chlorhexidine gluconate'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:33:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'ventilator associated pneumonia prevention'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '15'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mL (mL)'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:33:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '9 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '12 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:33:52
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:33:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:33:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:33:52

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 13:18:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:18:59
Data point term sent to Coder	System	20 Apr 2021 12:35:10
User entered 'meloxicam; Mobic'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:34:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'left total hip arthroplasty revision with incision and debridement and polyethylene exchange'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:34:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '15'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '10 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '13 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:34:55
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:34:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:34:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:34:55

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 13:16:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:16:04
Data point term sent to Coder	System	20 Apr 2021 12:36:11
User entered 'methocarbamol'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:35:58

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'left total hip arthroplasty revision with incision and debridement and polyethylene exchange'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:35:58

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '500'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'other (OTHER)'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'every evening at bedtime'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '17 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Apr 2021 18:47:17
	(b) (4)	
User entered '11 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '26 Apr 2021' reason for change: Data Entry Error	Angela Snyder (b) (4)	26 Apr 2021 18:47:17
	(b) (4)	
User entered '13 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:35:58
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:35:58

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:35:58

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:35:58

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN HYDROCHLORIDE, PRODUCTSYNONYM: CIPROFLOXACIN HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 12:50:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 12:50:03
Data point term sent to Coder	System	20 Apr 2021 12:39:13
Data point term sent to Coder	System	20 Apr 2021 12:38:12
User entered 'ciprofloxacin hcl'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'INFECTION/INFLAMMATION DUE TO INTERNAL LEFT HIP PROSTH, INIT (MRSA AND PSEUDOMONAS)' reason for change: Data Entry Error	Angela Snyder (b) (4)	20 Apr 2021 12:38:35
User entered 'INFECTION/INFLAMMATION DUE TO INTERNAL LEFT HIP PROSTH, INIT (mrsa and pseudomonas)' reason for change: Data Entry Error	Angela Snyder (b) (4)	20 Apr 2021 12:38:27
User entered 'infection/inflammation due to internal left hip prosth, init'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '750'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:37:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '13 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:37:40
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 12:37:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:37:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:37:40

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 13:16:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:16:05
Data point term sent to Coder	System	20 Apr 2021 12:40:13
User entered 'methocarbamol'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:39:23

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'left total hip arthroplasty revision with incision and debridement and polyethylene exchange'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:39:23

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '500'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'twice daily (BID)'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '14 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '16 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:39:23
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 12:39:23

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 12:39:23

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 12:39:23

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Apr 2021 13:16:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:16:05
Data point term sent to Coder	System	20 Apr 2021 12:40:14
User entered 'methocarbamol'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:40:07

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'left total hip arthroplasty revision with incision and debridement and polyethylene exchange'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:40:07

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '500'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'other (OTHER)'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:40:07

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'every evening at bedtime'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Oral (ORAL)'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '17 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	20 Apr 2021 12:40:07
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:40:07

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:40:07

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:40:07

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
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)	27 Apr 2021 00:27:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 00:27:51
Data point term sent to Coder	System	26 Apr 2021 18:50:26
User entered 'aspirin'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Blood clot prevention post surgical procedure; status left total hip arthroplasty revision with incision and debridement and polyethylene exchange'	(b) (4) Angela Snyder (b) (4)	26 Apr 2021 18:50:11

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '325'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'mg (mg)'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'once daily (QD)'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'Oral (ORAL)'	(b) (4) Angela Snyder (b) (4) (b) (4)	26 Apr 2021 18:50:11

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

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

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '26 Apr 2021'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '0'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered empty.	(b) (4) Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'No (N)'	Angela Snyder (b) (4)	26 Apr 2021 18:50:11
	(b) (4)	

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:50:11

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:50:11

US3662032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:19:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 18:50:11

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:19:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:40
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
Signature has been broken.	Angela Snyder (b) (4)	25 Mar 2021 18:29:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4)	25 Mar 2021 18:29:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	22 Feb 2021 14:56:35
User entered 'No (N)'	Brenda Miller (b) (4)	23 Sep 2020 16:00:35

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '10 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:30:36

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left hip xray'	Angela Snyder (b) (4)	25 Mar 2021 18:30:36

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	25 Mar 2021 18:30:36

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'post surgical follow up'	Angela Snyder (b) (4)	25 Mar 2021 18:30:36

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:01
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:31:07

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:01
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left hip and pelvis xray'	Angela Snyder (b) (4)	25 Mar 2021 18:31:07

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:01
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	25 Mar 2021 18:31:07

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:01
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:31:07

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:31:31

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'left total hip arthroplasty'	Angela Snyder (b) (4)	25 Mar 2021 18:31:31

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	25 Mar 2021 18:31:31

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:04
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:31:31

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '5 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:32:15

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'fluro extremity scan of left hip'	Angela Snyder (b) (4)	25 Mar 2021 18:32:15

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	25 Mar 2021 18:32:15

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:08
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'post surgery procedure for confirmation'	Angela Snyder (b) (4)	25 Mar 2021 18:32:15

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '3 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:33:02

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'knee bilateral 1 or 2 views xray'	Angela Snyder (b) (4)	25 Mar 2021 18:33:02

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Other (OTHER)'	Angela Snyder (b) (4)	25 Mar 2021 18:33:02

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'pre op prevention site facture care protocol'	Angela Snyder (b) (4)	25 Mar 2021 18:33:02

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '6 Nov 2020'	Angela Snyder (b) (4)	25 Mar 2021 18:33:35

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'hip bilateral 3 or 4 view xray'	Angela Snyder (b) (4)	25 Mar 2021 18:33:35

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Medical History (MH)'	Angela Snyder (b) (4)	25 Mar 2021 18:33:35

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:21
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:33:35

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered '3 Mar 2021'	Angela Snyder (b) (4)	25 Mar 2021 18:34:10

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'chest 2 view pa and lat xray'	Angela Snyder (b) (4)	25 Mar 2021 18:34:10

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	25 Mar 2021 18:34:10

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:47:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:47:48
User entered empty.	Angela Snyder (b) (4)	25 Mar 2021 18:34:10

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '7 Apr 2021'	Angela Snyder (b) (4)	14 Apr 2021 13:46:18
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'x-ray left hip'	Angela Snyder (b) (4)	14 Apr 2021 13:46:18
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	14 Apr 2021 13:46:18
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	14 Apr 2021 13:46:18
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	14 Apr 2021 13:46:44
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'revised hip joint replacement'	Angela Snyder (b) (4)	14 Apr 2021 13:46:44
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	14 Apr 2021 13:46:44
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	14 Apr 2021 13:46:44
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:06:43
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'hip lt 3 or 3 vw'	Angela Snyder (b) (4)	20 Apr 2021 12:06:43
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	20 Apr 2021 12:06:43
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:06:43
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '8 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:07:46
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'LEFT HIP ARTHROPLASTY REVISION WITH INCISION AND DEBRIDEMENT AND POLYETHYLENE exchange' reason for change: Data Entry Error User entered 'left hip arthroplasty revision with incision and debridement and polyethylene'	(b) (4)	
	Angela Snyder (b) (4)	20 Apr 2021 12:07:59
	(b) (4)	
	Angela Snyder (b) (4)	20 Apr 2021 12:07:46
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	20 Apr 2021 12:07:46
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:07:46
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:19:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered '11 Apr 2021'	Angela Snyder (b) (4)	20 Apr 2021 12:08:37
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:19:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered 'picc line placement confirmed with chest x-ray'	(b) (4) Angela Snyder (b) (4) (b) (4)	20 Apr 2021 12:08:37

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:19:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4)	20 Apr 2021 12:08:37
	(b) (4)	

US3662032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:19:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
	(b) (4)	
User entered empty.	Angela Snyder (b) (4)	20 Apr 2021 12:08:37
	(b) (4)	

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'USA-US088-2021-MRNA-1273-P301000012'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Carl'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Fichtenbaum'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '231 Albert Sabin Way'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Cincinnati'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '45267'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:16:28
User entered 'US'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 12:57:20
User entered '3'	System	21 Apr 2021 17:06:17
User entered '2'	System	15 Apr 2021 12:17:03
User entered '1'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'USA-US088-2021-MRNA-1273-P301000012'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Carl'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Fichtenbaum'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '231 Albert Sabin Way'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Cincinnati'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '45267'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:16:28
User entered 'US'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 12:57:20
User entered '3'	System	21 Apr 2021 17:06:17
User entered '2'	System	15 Apr 2021 12:17:03
User entered '1'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:19:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered '14/Apr/2021 11:11'	(b) (4) System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:19:44

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)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 12:16:28
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'USA-US088-2021-MRNA-1273-P301000012'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Carl'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Fichtenbaum'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '231 Albert Sabin Way'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Cincinnati'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '45267'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:16:28
User entered 'US'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 12:57:20
User entered '3'	System	21 Apr 2021 17:06:17
User entered '2'	System	15 Apr 2021 12:17:03
User entered '1'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:19:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered '15/Apr/2021 08:17'	(b) (4) System	15 Apr 2021 12:17:03

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:19:44

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)	22 Apr 2021 12:57:09
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 12:17:03

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'USA-US088-2021-MRNA-1273-P301000012'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Carl'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Fichtenbaum'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '231 Albert Sabin Way'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Cincinnati'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '45267'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:16:28
User entered 'US'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 12:57:20
User entered '3'	System	21 Apr 2021 17:06:17
User entered '2'	System	15 Apr 2021 12:17:03
User entered '1'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:19:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered '21/Apr/2021 13:06'	(b) (4) System	21 Apr 2021 17:06:17

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:19:44

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)	28 Apr 2021 13:39:08
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 12:57:09
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 17:06:17

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'USA-US088-2021-MRNA-1273-P301000012'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Yes (Y)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'No (N)'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Carl'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Fichtenbaum'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '231 Albert Sabin Way'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered 'Cincinnati'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:11:18
User entered '45267'	System	14 Apr 2021 15:10:59

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:02:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:16:28
User entered 'US'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:19:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 12:57:20
User entered '3'	System	21 Apr 2021 17:06:17
User entered '2'	System	15 Apr 2021 12:17:03
User entered '1'	System	14 Apr 2021 15:11:23

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:19:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	28 Apr 2021 13:39:08
User entered '22/Apr/2021 07:57'	(b) (4) System	22 Apr 2021 12:57:20

US3662032

Folder: SAE USA-US088-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:19:44

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)	28 Apr 2021 13:39:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:57:20